Best Practices in Funding Extramural Research

An on-line manual for NCI staff on grant review, funding and administration

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National Cancer Institute (NCI)
Bethesda, Maryland 20892

National Institutes of Health (NIH)
Bethesda, Maryland 20892

Department of Health and Human Services

Printing

Print/View **Best Practices in Funding Extramural Research** in Adobe Acrobat Portable Document Format (PDF) (674 K)
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Requirement

- Adobe Acrobat Reader is required to view the PDF file. If you don't have Acrobat reader, you can download it free of charge from the Adobe Web site.

Contact Us

To contact the Extramural Best Practices Web site staff

Please send email to Robin Brown if you:

- Were unable to find the information you were looking for.
- Found errors that need to be corrected.
- Noted points at which important information was missing.
- Have suggestions for making the Best Practices Web site more useful.

Receipt and Review of Unsolicited Applications

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Communicating about Applications Prior to Submission

Before applications are submitted, applicants may wish to discuss their research plans or the review process with members of the NCI staff. And, in certain circumstances, PDs must notify members of the review staff that particular applications should be assigned to their program areas.

This section describes both the general character of permissible communications between applicants and NCI staff and specific requirements for communications between program staff and review staff.

Communication between Program Staff and Applicants

Program directors are the primary contacts between applicants and NIH Institutes and Centers (IC). Before submitting applications, investigators may get in touch with an NCI Program Director (PD) to request information about:

- Funding mechanisms such as R01 investigator-initiated grants, P01 program project grants, K08 training grants.

- Submission requirements for applications.
- Interest in sponsoring the proposed research within a particular Institute or Center.
- Assignment of applications to particular review groups. For a list of Center for Scientific Review (CSR) groups, see http://www.csr.nih.gov/committees/rosterindex.asp.

PDs **may not** suggest particular experiments or lines of investigation. Information about unpublished research or lines of investigation being pursued by other research groups **must not** be divulged.

PDs **may**, however, discuss the aims of an application and its relationship to NCI goals and programs. PDs may also inform applicants about NCI Program Announcements (PAs), Requests for Applications (RFAs), and requests for special competing supplements.

For information about communicating with applicants after applications have been assigned to review groups, see Notifying Applicants about Assignment to Scientific Review Groups.

Communication between PDs and CSR (Use of ARA Form)

In certain circumstances, PDs must or may wish to notify the Center for Scientific Review (CSR) about the anticipated receipt of certain applications by sending an Awaiting Receipt of Application (ARA) Form to the Center.

Sending an ARA may be desirable when:

- The PD has discussed the proposed research with the applicant and has determined that the topic is consistent with the aims of his or her program area.

There are several circumstances in which sending an ARA is mandatory. The level of approval required depends on the type of grant and the size of the budget request.

An ARA regarding an application (submitted under any mechanism) must be approved by the division director if:

- Direct costs for the research proposed in the application equal or exceed $250,000.

In approving the application, the director indicates that, if the application receives a priority score within the payline the project could be funded.

In addition, applications must be approved by the Extramural Division Directors (EDD) if:

- The application is an R01 and the budget request exceeds $2.5 million in direct costs.
- The application is a P01 and the budget request exceeds $6 million in direct costs.

In approving the ARA, EDD indicates that, if the application receives a priority score that puts it within the payline, the project could be funded.

Communication between Applicants and CSR or NCI Review Staff

CSR or NCI review staff may be asked to explain the review process to applicants. Review staff may respond to these inquiries by phone or email. For additional information, applicants may be referred to the relevant websites.

- For CSR review procedures, direct applicants to http://www.csr.nih.gov.
- For NCI Division of Extramural Activities (NCI DEA) review procedures, direct applicants to http://deainfo.nci.nih.gov.

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Assigning Applications to Review Groups within NIH

All applications are initially submitted to CSR at the National Institute of Health. For detailed information about CSR procedures for assigning applications to Scientific Review Groups (SRGs), see http://www.csr.nih.gov/srabook/ch4a.htm.

Depending on the type of application and the specified funding mechanism, applications are then referred to SRGs or Special Emphasis Panels (SEPs). SRGs are committees made up of experts who participate in reviews of applications on particular topics over a period of several years. SEPs are convened for one-time meetings to review applications on a specific issue. The procedures for processing and reviewing grants in SRGs and SEPs are identical. Because most proposals are reviewed in SRGs, that term is used here to refer to both kinds of review groups.

The topic of applications to be reviewed by a particular SRG is established by official guidelines. In some cases, however, an applicant may request that his or her application be referred to a specific SRG. Applicants who wish to discuss the assignment of applications to SRGs should be encouraged to contact the CSR Division of Receipt and Referral or the Scientific Review Administrator (SRA) for the SRG to which he or she wants the application to be assigned. SRAs may consult with PDs to assess the appropriateness of the assignment requested by the applicant.

Processing Applications in the CSR Division of Receipt and Referral

After applications are logged into IMPAC II, CSR referral officers assign each application to the appropriate IC and then determine whether it should be reviewed within CSR or by the IC.

CSR manages the review of most:

- Investigator-initiated R01 applications.
- R01 applications submitted in response to PAs.
- Small Business Innovation Research and Small Business Technology Transfer applications.· Pre- and post-

doctoral fellowship applications.

If the application is to be reviewed within CSR, the applicant may request that it be assigned to a particular IC, and, subsequently, to a particular study section.

NCI DEA manages the review of applications for:

- Projects outlined in certain PAs or RFAs.
- Specialized Programs of Research Excellence (SPORE).
- Centers for basic and clinical cancer research.
- Multi-center clinical trials.
- Multi-project programs.
- Support of scientific conferences.
- Training and career development.

NCI DEA also manages merit reviews for research and development contracts submitted in response to Requests for Proposals (RFPs).

Notifying Applicants about Assignment to Scientific Review Groups

Within ten days after the application is assigned to a study section, CSR notifies the applicant and the sponsored research officer at his or her institution of the application number (e.g., 1 R01-CA12345-01), as well as its SRG and IC assignments.

An applicant may contact the PD to request that an application that has already been assigned to a particular IC and SRG be reassigned. In such cases, the PD should recommend that the applicant contact (1) the CSR Division of Receipt and Referral, (2) the SRA for the SRG to which the application was assigned, or (3) the SRA for the SRG to which the applicant would like the application to be assigned. The PD may aid in this process by consulting with the SRA.

CSR Division of Receipt and Referral
301- 435-0715
CSR Division of Receipt and Referral Homepage
http://www.csr.nih.gov/refrev.htm

CSR Referral Guidelines
http://www.csr.nih.gov/review/irgdesc.htm

Listing and Description of CSR Review Groups
http://www.csr.nih.gov/review/IRGDESC.asp

Telephone and email directory for CSR staff
http://www.csr.nih.gov/phone/phone.asp

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Processing Applications Assigned to NCI

CSR sends all applications assigned to NCI to the Review Processing and Distribution Unit (RPDU) in the NCI DEA. For some of these applications, NCI will be the primary assignment. In other cases, NCI will be the secondary assignment.

Receiving, Recording, and Storing Applications

After receiving the applications assigned to NCI from CSR, RPDU staff members:

1. Send the original copies of applications whose primary assignment is NCI to the NCI Records Management Center.
2. Transmit applications to the NCI Referral Office, which is located in the Program Coordination and Referral Branch.

Assigning Applications to Program Areas

Assigning applications to program areas is an interactive process involving an NCI Referral Officer and PDs in relevant sections, branches, and divisions.Upon receipt of the application, the referral officer:

1. Determines which program area is best suited to review the application.
2. Enters the assignment into the NCI Online Workplace (NOW) database, which can be accessed at http://cii.nci.nih.gov.
3. Assembles two copies of the application.
4. Attaches a cover sheet identifying the program area to which the application has been assigned.
5. Sends the package containing the two copies of the application and the cover sheet to the branch chief in the relevant program area.

Accepting Applications in Program Areas

PDs decide whether the division, program, or branch that they head will consider the application for inclusion in their portfolio.

If the referral is deemed appropriate, the PD identifies the application as accepted in NOW (http://cii.nci.nih.gov), and the NOW database automatically updates the IMPAC II database. If the referral is considered incorrect, the PD rejects the assignment in NOW and returns it to the NCI Receipt and Referral Office or passes it on to a more appropriate program area.

If the application seems suitable for more than one cancer activity, the referral officer assigns a maximum of two cancer activities, and program directors in the respective areas decide which area should accept the application. The PD who releases the application must indicate that it has been released in NOW before the accepting PD accepts the assignment.

Changing the Status of Applications

A change in the status of an application may be requested by the applicant or initiated by NCI staff.

- Before an application is reviewed, an applicant may simply request that an application be withdrawn or may submit an amended application and request that the previous application be withdrawn. Such a request should be filed with CSR.
- If an application has been reviewed and funded, an amended application on the same topic will be inactivated by NCI staff.

In either case, the status of an application must be changed to "Administratively Withdrawn" in IMPAC II. For applications that are withdrawn by the applicant before they are reviewed, CSR will enter the change. For applications that have been reviewed, PDs should coordinate with the NCI Referral Office to ensure that the status of the application is changed.

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Preparing for Review Meetings at NCI

The review of applications submitted to NIH is managed by SRAs in CSR or in the NCI Division of Extramural Activities.

This section focuses on review procedures within NCI, but occasionally refers to or provides links to descriptions of CSR procedures. For a description of the kinds of applications reviewed in the two processes, see Processing Applications within the CSR Division of Receipt and Referral.

Selecting Reviewers

Selecting reviewers is an informal process. The SRA is responsible for staffing the SRG in such a way that the

expertise required to provide a fair and thorough review for each application is represented at SRG meetings.

The SRG is a standing committee, the composition of which changes gradually over time as old members resign and new members are added. To constitute this body, the SRA relies on his or her knowledge of the research area, on advice from other SRAs and administrators in NCI DEA, and on suggestions from current members of the SRG or other experts in the research area.

In addition to shaping the standing committee, the SRA must, in some cases, recruit consultants whose expertise may be required to evaluate a particular application or a subset of the applications to be considered at a particular meeting.

Specifying Criteria for Reviewers

To ensure an efficient and effective review process, SRAs must distribute both applications and instructions for writing reviews 4-6 weeks in advance of the SRG meeting. A PDF file containing instructions for reviewers is available at http://grants.nih.gov/grants/peer/.

These instructions specify both the criteria to be used in assessing applications and the format to be used in preparing critiques. Reviewers may be asked to post their critiques on a website prior to the SRG meeting, but critiques must also be submitted in writing or on computer diskettes at the meeting.

Reviewers are not required to describe the project. In some cases, however, the description included in the application does not adequately describe the project. In those situations, reviewers should provide a fuller or more accurate description before addressing the review criteria. Further, if late-arriving material or other clarifications by the applicant during the review indicate that the orientation of the project has shifted, reviewers should briefly summarize those changes.

This section include specifies the criteria that reviewers are to use in evaluating applications.

Assessing the Scientific Merit of Applications

Judgments about the scientific merit of applications are to be based on the following criteria:

- The significance of the goals of the proposed research from a scientific or technical standpoint.
- The adequacy of the approach and methodology for the proposed research.
- The innovativeness and originality of the proposed research.
- The qualifications and experience of key personnel.
- The scientific environment and the availability of resources necessary to the research.

For an expanded discussion of these criteria, reviewers may be directed to http://grants.nih.gov/grants/guide/notice-files/not97-010.html.

Assessing the Appropriateness of Budgets and Project Schedules

In addition to assessing the scientific import of applications, reviewers must comment on the appropriateness of the budget and the proposed duration of the research in relation to the description of the project.

Assessing the Adequacy of Protections for Human Subjects

Certain categories of research involving human subjects are exempt from the federal regulations that require applicants to specify plans for protecting human subjects from research risks.

If an applicant has indicated that the proposed research is exempt, reviewers must determine whether the research plan is consistent with the description of one or more of the exemption categories. These categories are:

- Exemption 1 (E1)

  Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- Exemption 2 (E2)

  Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- Exemption 3 (E3)

  Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2)(b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- Exemption 4 (E4)

  Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- Exemption 5 (E5)

  Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

- Exemption 6 (E6)

> Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If the information provided regarding the involvement of human subjects is consistent with one or more of these descriptions, the reviewer should indicate the exemption category (or categories) using the appropriate code(s), i.e., E1, E2, and so on.

If the information provided regarding the involvement of human subjects is not consistent with one or more of these descriptions, the reviewer should indicate why the exemption is unjustified using the format specified in the instructions for reviewers.

If the applicant has not specified that the proposed research is exempt, reviewers must assess the adequacy of the research plan with regard to the privacy, physical safety, and psychological well-being of the participants. If the research plan involves unacceptable risks or inadequate protections, reviewers must describe these problems in their critiques using the format specified in the instructions for reviewers.

Assigning Codes to Indicate the Composition and Appropriateness of Participant Groups

If the application involves human subjects, the applicant must present a plan for selecting or recruiting participants in a way that is consistent with NIH policies regarding the inclusion of women, members of minority groups, and children in clinical research.

Reviewers are to report their judgments about the acceptability of these plans using the coding system specified in the instructions for reviewers. The codes reflect both specific facts about the application (e.g., no children are included in the anticipated participant group) and the reviewers' judgments about the acceptability of the research plan.

Judgments about the acceptability of the composition of a participant group depend on the purpose of the research, the state of present knowledge with regard to the research issue in question, and the risk to individuals in particular demographic groups of participating in the research.

Judgments of acceptability are especially consequential in Phase III clinical trials because, in these trials, large numbers of people may be exposed to treatments whose value has been tested only in small, carefully controlled studies.

The NIH definition of clinical trials is as follows:

> For the purposes of this policy, a clinical trial is a broadly based prospective Phase III clinical investigation for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population?based intervention trials are also included.

In judging the acceptability of the composition of participant groups for Phase III clinical trials, reviewers should be reminded to consider these scientific, social and medical factors:

- **Evidence of group differences.**

  Available evidence strongly indicates differences in the effect of the intervention based on gender, race, or ethnicity. These differences may have important implications for public health policy or clinical practice. To be acceptable, the study must be designed and the participant group must be constituted so as to permit a valid analysis of the effects of the intervention in both genders or in appropriate minority groups.

- **Evidence of no group differences.**

  Available evidence strongly indicates there are no differences in the effect of the intervention based on gender, race or ethnicity that might significantly influence public health policy or clinical practice. In this situation, gender, race, and ethnicity are not required as criteria for the selection of subjects, but the investigators should be encouraged to include individuals of both genders and of diverse racial and ethnic groups in the study sample, and to include these variables in coding the data.

- **No clear evidence regarding group differences.**

  There is no clear-cut scientific evidence to rule out differences that might affect public health policy or clinical practice in the effects of the intervention based on gender or membership in particular racial or ethnic groups. Members of particular demographic groups must be included in the projected participant group in sufficient numbers to permit researchers to detect any differential effect of the intervention that may exist.

- **Exclusion for health protective reasons.**

  One gender or some minority groups or subgroups are excluded from the study because inclusion of these individuals might impose unwarranted risks to their health or because including members of a particular group is inconsistent with the purpose of the research. For example, girls and women of childbearing age might be excluded from research involving treatments that might affect female fertility.

Assessing the Adequacy of Protections for Laboratory Animals

If vertebrate animals are included in the research, reviewers must ensure that the applicant describes the type and number of animals to be used, provides a rationale for choices regarding the use of animals, and specifies procedures to insure that animals are well cared for and do not experience unwarranted pain or distress.

If reviewers determine that certain aspects of the plan are incompatible with NIH policies governing the welfare of laboratory animals, they should describe these problems in their critiques, using the format specified in the instructions for reviewers.

Publishing Notices about Review Meetings

Publication of notices about review meetings is required by law. In most instances, meeting notices must be published in the Federal Register at least 15 days before the meeting. However, in special circumstances imposed by review and funding cycles, the 15-day requirement may not apply.

To meet publishing requirements, the Grants Technical Assistant (GTA) must submit the required information to the Committee Management Office (CMO) of the DEA.

- For SRG meetings, submit meeting notices to CMO 40 calendar days before the meeting.
- For SEP meetings, submit meeting notices to CMO 30 calendar days before the meeting.

For more information about the requirements for publishing notices in the Federal Register, refer to http://www.csr.nih.gov/srabook/ch10.htm.

Assessing Compliance with Administrative Requirements (Review by SRA)

Before review meetings, the SRA must examine each application to insure that applicants have met the administrative requirements relevant to the type of grant they are seeking. If the applications are sent in response to an RFA or PA or are to be reviewed by a standing committee, the SRA can remind all applicants (by letter or email) of the need to address these requirements. SRAs should not, however, contact individual applicants.

Before awards can be issued, applicants will be required to obtain approval for their projects from the Institutional Review Board (IRB) at their institutions. For research that involves human subjects, applicants will also be required to certify that all key personnel have completed training in the protection of human subjects. This information need not be submitted prior to the review meeting.

This section specifies the topics to be considered in the SRA's administrative review.

Procedures for the Participation and Protection of Human Subjects

If **Item 4** on the face sheet of the application indicates that the proposed research involves human subjects, the SRA must first determine whether the applicant has indicated that the research is exempt from the federal regulations that require applicants to specify plans for protecting human subjects from research risks.

If the applicant has not indicated that the research is exempt, the applicant must address the six topics specified under the **Human Subjects** heading on the application form. The six topics are:

1. Subjects - Applicants must specify the characteristics of participants in the proposed investigation. The applicant must discuss:

    - The representation of women and members of minority groups.

      NIH requires that women and members of minority groups and their subpopulations have the opportunity to participate in all research conducted or funded by NIH.

      If women and members of minority groups are not included among the participants, the applicant must justify this decision. This justification must be presented in terms of the health of the potential participants or the purpose of the research. For instance, women could reasonably be excluded from a study of prostate cancer.

      If the anticipated proportion of women and members of minority groups in the participant group is lower than the proportion that might be expected based on the demographic characteristics of the surrounding geographic area(s), the applicant must specify a plan for recruiting more participants.

      If Phase III clinical trials are proposed, women and members of minority groups must be included in

numbers such that analysis of the research results could reliably determine whether the effects of an intervention differ on the basis of gender, race, or ethnicity.

For further details, about the inclusion of women and members of minority groups, check the official guidelines at http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm.

The applicant must display the anticipated gender and ethnic composition of the participant group using the **Inclusion Report Format**. For an example of this display, see http://grants.nih.gov/grants/funding/phs398/section_3html#humansub.

- The participation of children.

  NIH requires that children (individuals under 21 years of age) be included in all research conducted or funded by NIH unless there are scientific or ethical reasons to exclude them. When children are included, they must be included in sufficient numbers to contribute to a meaningful analysis of the research results.

  Applicants must include a section titled **Participation of Children**. This section should describe and explain the applicant's plan to include or exclude children of a specific age range.

  The plan for the inclusion of children must describe the investigator's expertise in dealing with children who are in the age range of those who would participate in the study and must also describe the facilities available for accommodating children.

  For more information about NIH policies on the inclusion of children in research involving human subjects, see http://grants.nih.gov/grants/guide/notice-files/908-024.html.

- Criteria for including and excluding individuals from the research other than demographic characteristics.

  Such criteria might include diagnosis, medical history, current use of certain medications, or other factors that might involve undue risk to the participants, bias the results of the study, or interfere with clear interpretation of the results.

2. Sources of data - The applicant must specify:

   - The kinds of data that will be collected, e.g., samples of blood, or other bodily substances, medical images, participant reports of their experience while they are participating, reports of interviews with participants, observational ratings, videotape recordings or any other means of obtaining information relevant to the identification, selection, assignment to treatment conditions, or experience of participants.

   - Methods for coding or otherwise identifying the data so that the confidentiality of participants is protected.

3. Plans for recruiting participants and obtaining informed consent - The applicant must identify:

   - Organizations (e.g., hospitals, clinics, community groups) at which participants have voluntarily appeared or that will be asked to refer potential participants.

- Plans for obtaining informed consent from participants or their guardians, for obtaining assent from children or other individuals not legally eligible to provide informed consent, and, in some cases, from treatment providers.

- Procedures for informing participants that they may withdraw from the research at any point.

4. Potential risks - The applicant must specify:

    - Risks to the privacy of patients.

    - Risks to the physical safety of research participants.

    - Risks to the psychological well-being of research participants.

5. Procedures to minimize risk - The applicant must specify:

    - Plans for responding to untoward events that threaten the physical safety or psychological well-being of participants.

    - Plans for monitoring the confidentiality of data collected from or about the participants before, during, or after the investigation.

    - Plans for monitoring to insure the safety of participants in clinical trials. The type of monitoring depends on the size and complexity of the trial and on the degree of risk to participants.

      Phase I and Phase II studies require a **Data and Safety Monitoring Plan (DSMP)**, which may be administered by the investigator, by a project manager, by a member of the NCI program staff, or by an individual designated by the investigator or NCI staff. Or, some combination of these individuals may work together to administer the plan.

      A **Data and Safety Monitoring Board (DSMB)** is required for all Phase III clinical trials. Phase III trials are tests of interventions which, if found to be successful, would likely influence clinical or public health practice.

      For more information about the topics to be included in the discussion of data and safety monitoring, see http://cancertrials.nci.nih.gov/researchers/dsm/index.html.

6. Costs of Potential Risks versus Benefits of the Study - The applicant must describe:

   The relationship between risks to the individual participants in relation to benefits that might accrue to the participant and in relation to the significance of the results. The significance of the research results may be discussed in terms of contributions to scientific knowledge, public health benefits, or both.

   For more information on the participation and protection of human subjects, see http://grants.nih.gov/grants/peer

Procedures for the Lawful Use of Fetal Tissue

Researchers and their institutions must comply with the law governing the use of fetal tissue in research.

The statute prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for **valuable consideration**. Valuable consideration is a concept similar to profit. It does not include reasonable payment for the cost of collecting, processing, preserving, storing, or transporting these tissues. Individuals who violate this law by acquiring, receiving, or transferring fetal tissue for valuable consideration may face criminal penalties.

An authorized official at the applicant's institution must certify that the proposed research would comply with the law by signing the face page of the application.

For more information on the provisions of this statute, see http:/grants.nih.gov/grants/guide/notice-files/not93-235.html.

The SRA must notify the Associate Director for Review, Referral and Program Coordination of NCI DEA of any applications involving the use of fetal tissue.

Procedures for the Lawful Use of Human Embryonic Stem Cells

NIH policies for the use of human embryonic stem cells are being developed. The stem cell lines currently approved for research purposes are listed at the following website.

http://www.nih.gov/news/stemcell/082701list.htm

Procedures for Ensuring the Welfare of Laboratory Animals

If **Item 5** on the face sheet of the application or proposal indicates that the proposed research involves vertebrate animals, the applicant must address the five topics specified under the **Vertebrate Animals** heading on the application form. The five topics are:

1. Description of Animals - The applicant must describe:
    - The proposed use of the animals in the work outlined in the Research Design and Methods section.
    - The species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justification of the Use of Animals - The applicant must explain:
    - The choice of species.
    - The number of animals to be used.

      If animals are in short supply, costly, or to be used in large numbers, the applicant must provide an additional rationale for their selection and numbers.
3. Veterinary Care - The applicant must describe:
    - Procedures for ensuring the health and safety of the animals.
4. Prevention of Unnecessary Suffering - The applicant must describe:
    - Procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is

unavoidable in the conduct of scientifically sound research.

- The use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

5. Euthanasia - The applicant must specify:

   - Any method of euthanasia to be used.
   - Reasons for the selection of this method.

     The applicant must indicate whether, if the research protocol calls for the euthanasia, the chosen method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If the chosen method is not consistent with these policies, the applicant must present a justification for not following the recommendations.

     For more information on the use of animals in research, see http://grants.nih.gov/grants/olaw/olaw.htm.

Specification of the Budget

Applicants who submit **budgets in which the direct costs do not exceed $250,000 per year** may use the modular budget process. In modular budgets, applicants request funds in $25,000 increments, and any increases or decreases to the budget that occur during the funding process are made in steps of $25,000.

The modular budget process can be used in applications for:

- Competing individual research grants (R01).
- Exploratory or developmental grants (R21).
- Small grants (R03).

Unsolicited, investigator-initiated applications with **budgets that exceed $250,000 per year** in direct costs must submit detailed budgets.

Both modular and detailed budgets must specify:

- Activities of Key Personnel

  Each member of the research team must be described in terms of position, role, and level of effort. Consultants and to-be-appointed personnel must be included. Information about individual salaries must not be included.

- Consortium and Contractual Costs

  An estimate of the total direct and indirect costs rounded to the nearest $1,000 must be provided. The budget must indicate whether each of the collaborating institutions is foreign or domestic.

  The total consortium/contractual costs must be included in the modular direct cost request. Variation in the number of modules requested in different years should be described and justified. For example, purchase of

equipment in Year 1 may result in a greater number of modules being requested in Year 1 than in subsequent years.

Biographical Sketches of Key Personnel

All applications, including those that use the modular budget process, must contain a biographical sketch of each of the key personnel associated with the project. This sketch can be up to three pages long. It should include a description of research relevant to the application that is currently being conducted or that has been completed during the past three years.

For an example of a biographical sketch, see:
http://grants.nih.gov/grants/funding/modular/modular.htm.

Checklist

The applicant must complete the checklist contained in Form 398. This form requires that the applicant specify the type of application being submitted, provide information about the institutional environment in which the research will be conducted, and describe the costs of conducting research in that environment.

Appendices

If appendices are included, there must be five collated sets. The application should include five collated sets of all appendices. The appendix is sent only to the members of the SRG who will serve as the primary reviewers of the application.

Appendices may not be used to circumvent the page limitations of the research plan. Graphs, diagrams, tables, and charts that do not need to be in a glossy format to show detail must be presented in the research plan, rather than in the appendix. An application that does not observe these limitations may be returned.

For new, amended, and competing applications, the following materials may be included in the appendix:

- Up to 10 publications, manuscripts (submitted or accepted for publication), abstracts, patents, or other printed materials directly relevant to this project. These may be stapled as sets.
- Surveys, questionnaires, data collection instruments, and clinical protocols. These may be stapled as sets.
- Original glossy photographs or color images of gels, micrographs, etc., provided that a photocopy (which may be reduced in size) is also included within the 25 page limit of the research plan. **No photographs or color images may be included in the appendix that are not also represented within the Research Plan.**

Specialized grant applications may require or permit the inclusion of other materials in the appendices.

Selecting Applications for Discussion: The Streamlined Review Process

A streamlined review process is used to identify applications to be discussed at the meeting of the SRG.

Before the meeting, the SRA asks reviewers to identify applications that they regard as being in the lower half in terms of the quality of applications customarily reviewed in their study section.

After receiving this information, the SRA distributes to all members of the SRG a list of applications identified as being in the lower half of the quality distribution by at least two of the assigned reviewers and readers. All SRG members are encouraged to review these applications carefully to ensure that this categorization is accurate.

In most cases, applications judged to be in the lower half before the meeting will not be discussed at the meeting. These applications are referred to as "unscored" indicating that they have not been discussed and will not be assigned scores in the voting that takes place at the meeting. If any member of the SRG does not concur with this evaluation, the application will be fully discussed at the meeting.

Applications in the upper half will be discussed at the study section meeting and will be assigned a priority score.

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Conducting Review Meetings

This section describes the procedures for conducting review meetings within NCI. For information regarding the conduct of review meetings managed by CSR, refer to http://www.csh.nih.gov/srabook.ch6.htm.

Establishing the Agenda for Review Meetings

The SRA will create an agenda specifying the order in which the applications will be discussed, listing the reviewers who are to present critiques of each application, and identifying individuals who have conflicts of interest with regard to particular applications.

Defining the Roles of Participants in Review Meetings

In keeping with federal regulations regarding the conduct of scientific meetings and the maintenance of personal privacy, SRG meetings are closed to the public. The authorized participants at a review meeting include:

- The Scientific Review Administrator (SRA)
- The Grants Technical Assistant (GTA).
- Reviewers
- NIH or NCI program representatives.

This section describes the roles of authorized participants.

Role of the Scientific Review Administrator

The SRA is legally responsible for ensuring that the SRG arrives at a sound recommendation in accord with NIH policy. The SRA:

- Provides guidance on review criteria, policy, and procedural matters.
- Records important points to be included in summary statements.
- Works with the chairperson to ensure that each application receives a thorough and objective review.
- Reminds reviewers to modify their written comments so as to reflect the views of the SRG.

At the beginning of each meeting, the **SRA** should:

1. Discuss the formal responsibilities of the SRG.

   The SRG is charged with advising IC staff on the scientific and technical merit of the applications under consideration. For applications that are scored, the SRG must recommend a budget and specify a time period for carrying out the proposed work.

2. Emphasize the confidentiality of the materials.

   Reviewers should be told that they are not to discuss the proceedings with anyone not involved in the review. In particular, they must not discuss the content of the discussion or the recommendations of the SRG with applicants. If contacted by an investigator, reviewers are to refer all questions to the SRA or Institute program staff.

3. Present the Public Health Service (PHS) conflict of interest policy.

   If a member's presence during the review of an application review would constitute a real or apparent conflict of interest, that member must leave the meeting during the discussion of the application.

   To comply with this requirement, the GTA maintains a record of those members who leave the meeting. At the end of the meeting, the GTA obtains certification from all consultants that they have been absent from, and have not participated in, the reviews of any application from an organization where they are employees, consultants, officers, directors, or trustees, in which they have financial interests, or for which they have any other conflict.

4. Specify the criteria for evaluating the scientific merit of proposals.

   These criteria are presented in Specifying Criteria for Reviewers.

5. Remind reviewers that comments on project budgets must be limited to the appropriateness of the budget based on the purpose of the research. Discussion of paylines or any other intrusion into administrative matters is inappropriate.

6. Remind the SRG about review and voting procedures, assignment of priority scores, and items such as human subjects, animal welfare, overlap with other grants, and, where appropriate, inclusion of women, members of minority groups and children in participant groups. Completeness and accuracy on the scoring sheet should be emphasized.

Role of the Grants Technical Assistant

The GTA:

- Maintains the confidentiality of the meeting by ensuring that only authorized individuals are permitted to enter the room.

- Ensures that individuals who have conflicts of interest with the application leave the room during the discussion and invites those individuals to return to the room when the discussion has ended.

- Maintains a record of people who attended all or a portion of the meeting. This information must be sent to the Scientific Review and Evaluation Award unit in the Committee Management Office of DEA.

- Maintains the security of materials used in the review process.

  If the SRA, GTA, and SRG members are absent from the room, the room must be locked. If the meeting lasts longer than a day, the room must be locked overnight.

- Ensures that all waste materials are properly disposed of and all essential materials are transported back to the SRA's office.

- Ensures that copies of all written reviews and computer diskettes containing written reviews have been turned in.

- Collects scoring sheets.

To insure confidentiality, the SRA or GTA must hand carry reviewers' comments, scoring sheets, and conflict of interest forms to the SRA's office at the end of the meeting.

- When SRG meetings are conducted as part of a site visit, a GTA may not be available. In such instances, the SRA carries out the duties of the GTA.

Role of the Chairperson

The chairperson is responsible for:

- Overseeing procedural aspects of the meeting. Such matters include:

  - Announcing the application to be discussed.

  - Reminding reviewers with conflicts of interest to leave the room.

  - Asking reviewers to present their reviews in the appropriate order, i.e., primary reviewers first, secondary reviewers second, and so on.

  - Moderating the discussion of applications.

  - Calling for votes.
- Leading the scientific discussion in which reviewers present their comments and the applications are discussed

by reviewers and other members of the SRG.

- Ensuring that the perspectives of all reviewers are weighed and that the recommendations of the SRG are well considered and clearly conveyed to the SRA.

- Determining whether concerns about the welfare of human or animal subjects reflect the views of the SRG. For concerns to be designated as such in coding the application (See Coding Applications after SRG Meetings), members of the SRG must be in consensus with regard to the concern.

Because the chairperson also reviews applications and votes, he or she may participate in, as well as preside over, discussions. If the chairperson must leave the room during the discussion of an application (e.g., because of a conflict of interest with regard to that application), the SRA appoints another member of the review panel to serve as acting chairperson. **The chairperson is not responsible for providing guidance on matters of review policy.**

Role of Reviewers

Much of the work of reviewers is done before the meeting of the SRG takes place. For a description of the judgments required of reviewers and the criteria used to make those judgments, see Specifying Criteria for Reviewers.

Each application will have been reviewed by a primary, secondary, and tertiary reviewer, and the reviewers present their critiques in this order. Reviewers discuss the application among themselves so that other members of the SRG can hear the perspectives and reactions of those who are most familiar with it. Reviewers also answer questions posed by members of the SRG or by the chairperson.

Reviewers may be asked by the SRA or the chairperson to modify their reviews to reflect the discussion of the SRG.

Role of NCI Program Staff

Members of the program staff may attend SRG meetings to listen to the discussion. In some cases, an IC may want several program staff members to attend the meeting. In such cases, the SRA must be consulted, and staff members must give their name and IC affiliation so that the record of attendees is complete.

During the review meeting, the SRA may request information from members of the program staff. If a member of the program staff wishes to address the SRG, he or she must request permission from the SRA before doing so.

Program staff may be asked to provide or may want to provide information about:

- The philosophy, development, and intent of IC programs and PAs.

- Other grant or contract support to investigators with applications under review.

- Scientific management of grants awarded to the applicant in the past.

NIH staff members must not attempt to influence the scientific evaluation of grants by the SRG, and SRG members must not discuss federally-funded activities at their own institutions with staff members.

NIH staff members, including extramural associates and extramural administrator trainees whose attendance is essential to carrying out their responsibilities, may also attend the meeting. These individuals must obtain permission to attend from the SRA.

Discussing the Scientific Merit of Applications at Review Meetings

To provide for an orderly discussion and fair review of applications, SRG meetings follow a formal procedure. The components of that procedure are described in this section.

Designating Applications as Unscored

As indicated under Selecting Applications for Review, reviewers will have identified applications that they believe to be in the lower half of the quality distribution typical of their SRG before the review meeting.

At the beginning of the meeting, the **chairperson** reads the list of these applications. If members of the SRG agree with this categorization, the application is designated as **unscored**, and no priority score is assigned

If any member of the SRG disagrees with the categorization of an application as unscored, the application will receive a full review.

Presenting Reviews of Applications

Applications that have been identified as being in the upper half of the quality distribution receive full discussion at the meeting of the SRG. To ensure consistency in the evaluation of applications, this discussion takes place in a pre-determined sequence. The steps in this sequence are:

1. The chairperson calls on the assigned reviewers, who begin by presenting the scores they have given to their applications.
2. These reviewers then present their prepared comments on an application.
3. After discussion among the reviewers, the chairperson invites comments and questions from the group.
4. The assigned reviewers again announce their scores.
5. After hearing the scores of those who have reviewed the applications, other members of the group vote.

Note that, in some instances, the discussion may lead to a decision to delete certain components of the research proposed in the application or to a decision to cancel or delay the vote.

For a description of these alternatives, see Voting on Applications.

Reviewing Amended Applications

An application may be amended and resubmitted twice. After the application has been considered in its original form, and in two subsequent amended versions, the application will not be reviewed again. Amended applications must be submitted no later than two years after the date of the original review.

Before an amended application can be submitted, the principal investigator must have received the summary statement from the previous review. The amended application must include an introduction of no more than three pages in which the applicant summarizes the changes in the application. The introduction must also include responses to the criticisms and issues raised in the summary statement.

Unless new conflicts of interest are identified, the amended application will be assigned to the SRG that reviewed the previous version. The procedures for reviewing amended applications are the same as those for a newly-submitted application.

Reviewing Applications form Foreign Institutions or from Domestic Institutions with Substantial Involvement of Foreign Institutions

During the initial review process, applications form foreign institutions will be evaluated and scored using the standard review criteria. During the review and award process, the application will also be evaluated in terms of whether the proposed research provides:

- Opportunities for advancing the state of knowledge in a particular domain through the use of talent, resources, populations, or environmental conditions that augment opportunities in the US or opportunities that are not readily available in the US.
- Opportunities to conduct research that is distinctly and specifically relevant to the mission of NCI.
- Opportunities to significantly advance the health sciences in the US.

Applications from foreign or international organizations will not be funded unless approved by the National Cancer Advisory Board, then by the Fogarty International Center (http://www.nih.gov/fci), and, in many cases, the Department of State.

As part of the summary statement, the SRG must provide, in an Administrative Note, a comment on special opportunities for research. If there are no special characteristics, this should be noted.

Voting on Applications

In most instances, voting will be straightforward. Reviewers will have agreed that the application is in the top half of the quality distribution and will assign priority scores to the application as written.

In some cases, however, reviewers may determine that certain parts of the project are not essential to the purpose of the research and recommend that those elements be deleted. In other cases, reviewers may not agree that an application should be in the category to which it has been assigned-either scored or unscored-before the meeting.

This section discusses each of these situations.

Assigning Priority Scores in the Streamlined Review Process

In most cases, reviewers will have identified the set of applications to be scored before the meeting of the SRG is held. If no objections to scoring an application arise during the meeting, reviewers assign scores that reflect the potential impact of the project on the research area(s) under the purview of the SRG. Reviewers record their scores in private, using as a guideline the scoring range defined by the scores of primary and secondary reviewers.

The full scoring range runs from 1.0 to 5.0, with 1.0 high. In the streamlined review process-that is, after the applications in the lower half have been identified-the full range of scores is not used because the lower half of applications has already been eliminated.

Instead, reviewers assign ratings between 1.0 and 3.0. A score of 3.0 means that an application is of average quality, based on the full range of scores. Reviewers are, however, free to "vote their conscience." That is, if a reviewer maintains that an application is not in the upper half, he or she is free to score it as desired.

Reviewers mark scores to two significant figures, e.g., 2.2. The individual scores are averaged and then multiplied by 100 to yield a single overall score for each scored application, e.g., 253.

Voting on Applications with Deleted Components

Occasionally, reviewers may determine that one or more components of an application is unnecessary, premature in relation to the current state of knowledge, or, for some other reason, not of sufficient scientific or technical merit. In these cases, they may recommend deleting those components.

Even with one or more components deleted, the research may still be judged to have significant scientific merit. In such situations, reviewers should assign priority scores to the proposal as if the unnecessary components had, in fact, been deleted, and should adjust the project budget accordingly.

If, however, deleting the unnecessary or unjustified elements would weaken the project to the extent that its scientific merit is greatly diminished, reviewers should score the project as written.

Note: In recommending that components of a project be deleted, reviewers should express their views in phrases such as "should not be supported." The phrase **Not Recommended for Further Consideration** is used to refer to cases in which, after discussion, reviewers determine that an application should not be scored.

Voting on Motions: Not Recommended for Further Consideration

Applications that had, at the outset of the meeting, been considered as being in the upper half of the quality distribution, may, after discussion, be seen as lacking significant scientific merit. If, after discussing an application, members of the SRG do not want to proceed to scoring a particular application, the application may be designated as **Not Recommended for Further Consideration (NR)**.

This designation may be appropriate if the SRG determines that:

- Hazardous or unethical procedures are involved.
- No additional funds can be recommended, such as in the case of a request for a supplement that is deemed unnecessary.
- The individual listed as Principal Investigator will not be responsible for the scientific and technical direction of the project.

To indicate that an application should be characterized as **Not Recommended for Further Consideration**, an individual must move to cancel the vote. Such a motion must be seconded and approved by the group. If the motion is carried, no priority rating is recorded and the budget is not discussed.

If the decision that an application will be designated as Not Recommended for Further Consideration is obtained by a split vote (i.e., a vote that is not unanimous) during the meeting, the SRA must report that vote in the heading of the Summary Statement. Any discrepancies between the vote obtained at the meeting and votes on scoring sheets submitted subsequently should be disregarded. No priority score would be computed for these applications.

If the members of the SRG vote to score the application, dissenting members will be encouraged to enter priority ratings. The reviewer may enter a score of 5.0 or another "outside the range" value that indicates his or her preference not to score the application.

If two or more members disagree with the majority recommendation as to whether the application should be designated as **Not Recommended for Further Consideration**, the dissenting members must prepare a minority report. This report should be attached to the Summary Statement.

Voting on Motions: Deferred for Further Information

If the SRG determines that it cannot vote on an application because the application does not provide the information required for a full and fair assessment, the application may be **Deferred for Further Information**. If the required information can be obtained quickly by telephone or email, a deferred application may be reconsidered in the same meeting.

If the information cannot be obtained during the meeting, the information may be obtained from the applicant by telephone at a later time, or the applicant may be invited to submit additional information. If the required information cannot be supplied in this way, conducting a site visit or obtaining a report from an expert who is not a member of the SRG may be necessary. In either case, the application would then be considered at the next meeting of the SRG.

Abstaining from Voting

All SRG members who are allowed to vote and are present for the discussion of an application are expected to vote and, if scoring is recommended, to record a priority rating.

Occasionally, however, one or more members may abstain because of a technical issue that is not resolved by the discussion or because of a lack of expertise in the specific area. In such cases, an abstention is permissible.

Members should neither abstain merely to avoid writing a minority report, nor should they abstain because they do not feel comfortable, for personal or professional reasons, voting on an application from a particular investigator. Instead, they should be considered as in conflict and should leave the room during the review of that application.

The SRA should guard against numerous abstentions on a given application or frequent abstentions by one member.

Addressing Allegations of Scientific Misconduct

Misconduct in science is defined as "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data." For more information about DHHS policies on scientific misconduct, see http://ori.dhhs.gov/html/misconduct/regulation_subpart_a.asp.

Although instances of scientific misconduct are rare, they are important. Allegations of such misconduct must, therefore, be reported and investigated.

To ensure fair peer review, however, reviewers must understand that investigating allegations of misconduct is the responsibility of NCI staff. Reviewers who believe that some misconduct has occurred must not discuss their beliefs with anyone other than the SRA before, during, or after the SRG meeting. Speaking openly about an unsubstantiated

claim is itself unethical.

Nonetheless, reviewers play an important role in detecting and deterring scientific misconduct. Allegations of misconduct should be brought to the immediate attention of the SRA in charge of the SRG. If possible, these allegations should be pointed out before the review meeting.

If apparent misconduct is discovered during the meeting, the reviewer should request a break and report the alleged misconduct to the SRA. If allegations of misconduct are raised in the discussion, evaluation of the application must be deferred.

Note that, as of this writing (September, 2001), policies on scientific misconduct are under review. For updates on these policies, consult the DHHS Office on Research Integrity website at http://ori.dhhs.gov.

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Making Budget Recommendations and Adjustments

After recording priority scores for an application, the SRG must recommend a budget. The recommendation should specify the duration for which support should be provided. Budget decisions, however, are the responsibility of NCI staff.

Making Budget Recommendations

The SRG is expected to comment on the budget, and, if needed, recommend adjustments. The SRG should confine its comments on budgets to the appropriateness of the budget for the research as proposed or as adjusted based on the deletion of particular components of the project. (For additional information on deleting components from applications, see Voting on Applications with Deleted Components.)

Reviews of applications that request supplemental funds must include comments on the supplement in relation to the originally approved budget.

Reviewing the Budget

In reviewing the budget, the SRG should determine:

- Whether the budget is sufficient given the description of the proposed project.
- Whether each item in the budget is required to accomplish the proposed research.

If particular budget items do not seem justified, they should be eliminated from the budget. Budget reductions may be recommended when:

- The SRG suggests deleting parts of a project.

- The applicant has provided insufficient information about work to be done in the second or later years of a project.
- Reviewers believe that the project can be accomplished with less expense and in less time than indicated in the application.
- Reviewers believe that preliminary data are required to demonstrate the feasibility of a project.
- Specific budget items do not appear to be justified given the description of the proposed research.

If reviewers believe that one of the positions listed in the application is unnecessary, or if the percent of effort for a particular member of the research appears to be higher than is necessary to carry out the research, the position should be deleted or the percent of effort should be reduced, even if no salary is specified.

If after review of the application by NCI staff, the position or the percent of effort is not reduced, salary can be requested later and awarded as a supplement to the grant.

Adjustments in Modular Budgets

Adjustments in modular budgets must be made in modules of $25,000. If the amount requested is believed to be too large, the number of modules should be reduced. Recommendations as to specific items or activities that should be reduced are not required.

If changes in the content (e.g., specific aims) or arrangements (e.g., staffing, consortium arrangements) are recommended, but a cost in modules cannot be estimated, recommendations for these changes should be presented in the budget section of the review without assigning an amount.

In recommending budget adjustments, the SRG should restrict its comments to the funding required to carry out the project as proposed or as amended based on judgments about the merit of particular elements of the project. If an application is funded, NCI staff will deal with issues such as scientific or budgetary overlap with an applicant's already funded projects.

Adjustments in Traditional Budgets

Reviewers may recommend reductions in the traditional budgets by identifying elements to be deleted or reductions in the cost of particular elements. In either case, reviewers must provide a rationale for their recommendations.

Adjustments in Period of the Award

Reviewers may recommend that the proposed period of the award be adjusted. For instance, an applicant may request funding for three years, but reviewers may feel that the proposed research could be completed in two years. In such a case, reviewers may recommend that the period of the award be reduced; such recommendations should be accompanied by a rationale for the reduction in time.

Reviewing Applications with Non-Compliant Budgets

Applications for awards that do not exceed $250,000 should use the modular budget process. If a non-modular budget has been submitted, reviewers will disregard the details of the budget or excess budget narrative, and will make

budget recommendations in modules.

If the budget narrative does not include required information (e.g., the percent effort of key personnel has been omitted), the SRA must request this information from the applicant.

For information on the preparation and format of a modular budget, see
http://grants.nih.gov/grants/funding/modular/modular.htm

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Recording the Results of Review Meetings

Following each SRG meeting, the data derived from the deliberations of the SRG must be recorded and reported to NCI administrators and the applicant. This section describes the steps required to carry out these tasks within NCI.

For details regarding the post-meeting activities managed by the Center for Scientific Review, refer to http://www.csr.nih.gov/srabook/ch7.htm.

Recording Priority Scores

Within three working days of the SRG meeting, the accuracy of the codes and priority scores assigned by the members of the SRG must be verified and entered into the IMPAC II system.

For each reviewer and each application, the data should include a priority score or the correct code. The codes are:

- UN - Noncompetitive
- NR - Not Recommended for Further Consideration
- DF - Deferred for Further Information
- AB - Abstention
- CF - Conflict of Interest
- NP - Not Present

IMPAC II will average the priority scores assigned by individual reviewers and multiply them by 100 to obtain the final priority score. After codes have been entered and scores have been computed, the GTA should check the score matrix for accuracy and completeness, and the SRA should verify this assessment.

For outlier scores, the SRA should contact reviewers to clarify the reasons for the scores. If the explanations suggest that the outlier scores were based on considerations other than scientific merit, the SRA should discuss the case with the appropriate DEA official, who may recommend deleting the score.

Recording Budget Recommendations

In reviews managed by CSR, only the requested budgets are entered into IMPAC II and included in the Summary Statement. Actual budget recommendations are determined by IC staff based on comments in the budget section of the Summary Statement.

In reviews managed by NCI DEA, the budgets recommended by the SRG need to be entered, verified, and released into the IMPAC II system within five working days of the meeting.

Because uniformity across SRGs is essential in calculating recommended changes in the budget and in reporting changes in summary statements, the following procedures should be followed:

- If the budget for personnel is to be reduced, the sum of the reductions in salary and fringe benefits should be deducted from the amount requested for this purpose during the first year of the project.

  If similar reductions in the personnel budget are recommended for subsequent years, the amount deducted should be the same as the amount deducted for the first year. Incremental increases that the applicant may have requested should be disregarded.

- If the budget for supplies, travel, consultants, or other expenses is to be reduced, the sum of the reductions should be deducted from the amount requested for these purposes during the first year of the project.

  If similar reductions in the budget are recommended for subsequent years, the amount deducted should be the same as the amount deducted for the first year. Incremental increases that the applicant may have requested should be disregarded.

For applications with non-compliant budgets, the SRA must include the following note:

The submitted budget was not compliant with the modular application procedures as announced in the December 15, 1998 NIH Guide for Grants and Contracts.

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Coding Applications after SRG Meetings

To insure that the views of the SRG are reported to NCI staff in a systematic way, each application must be coded to reflect the views of the SRG. The SRA enters codes that capture the SRG's assessment of the application with regard to the adequacy of the procedures specified for:

- Informing and protecting human subjects.
- Including women, members of minority groups, and children in the participant group.
- Including and excluding individuals with particular demographic or medical characteristics from clinical trials.

- Ensuring the welfare of animals.

The codes assigned by the SRA are based on the codes assigned to applications by individual reviewers. Although only a single code is reported, the "sense of the meeting" may be indicated in the summary statement.

The coding system to be used depends on the type of application. A single-component application is one in which the applicant requests funds for a single study. Multiple-component applications involve multiple studies. In addition, applications may specify funding mechanisms other than the usual procedure for R01 investigator-initiated applications. The coding systems to be used in each of these cases are specified below.

Coding Single Component Applications

This section specifies the codes to be used for applications in which the applicant requests funds for a single study.

- **Human Subjects**
  Use the following codes to characterize the procedures for informing and protecting human subjects described in the application.

Code	Explanation
10	No human subjects involved.
E1 - E8	Designated exemptions. See the explanation of exemption codes E1 - E6 on this website or in PHS Form 398. If multiple exemptions are designated, use E7. If regulations regarding the participation and protection of human subjects have been waived by the Secretary of DHHS, use E8.
20	Human subjects involved. No exemption designated.
30	Human subjects involved. Certified; no SRG concerns or comments. An appropriate Multiple Project Assurance is on file with OHRP. A certification of IRB review dated no earlier than one year prior to the receipt of the application is on file in the SRA’s office; human subjects protection is adequate.

44	Human subjects involved. Certified; SRG concerns. Assurance and certification requirements have been met. SRG has noted potential or actual unacceptable risks. Award will not be made until the problem is resolved.
49	Human subjects involved. Conditional award.
54	Human subjects involved. Previously coded 44; concerns now resolved.
59	Human subjects involved. Previously coded 49; concerns now resolved.

- **Inclusion of Women, Members of Minority Groups, and Children**

  Research exempted from regulations concerning the protection of human subjects is not exempt from NIH policies on the inclusion of women, members of minority groups, and children. To track the representation of individuals from these demographic categories in NIH-funded research, applications must be coded to reflect the composition of the participant group in the proposed research.

  Each application is assigned three alphanumeric codes. These codes characterize the participant group with regard to gender, status as a member of a minority or non-minority group, and age (i.e., child vs. adult). For each of the three codes, values specifying the demographic composition of the participant group are assigned.

  In addition, the application is coded with regard to the acceptability of the composition of the participant group given the purpose and type of the research.

  Use the following codes to characterize the composition of the participant group and the acceptability of that composition.

- **Coding with respect to gender**

First character	G

Second character	1 = Both genders
	2 = Only women
	3 = Only men
	4 = Gender composition of participant group unknown
Third character	A = Scientifically acceptable
	U = Scientifically unacceptable

- **Coding with respect to membership in a minority group**

First character	M
Second character	1 = Members of minority and non-minority groups
	2 = Members of minority groups only
	3 = Members of non-minority groups only
	4 = Racial or ethnic composition of participant group unknown
Third character	A = Scientifically acceptable
	U = Scientifically unacceptable

- **Coding with respect to age**

First character	C
Second character	1 = Children and adults
	2 = Children
	3 = No children included
	4 = Age composition of participant group unknown
Third character	A = Scientifically acceptable
	U = Scientifically unacceptable

Examples of codes that might be applied to specific applications are:

Code	Explanation
G1A	Both genders represented. Gender representation is acceptable in terms of scientific purpose of the research.
M3U	Only members of non-minority groups are included. Justification provided for exclusion of members of non-minority groups is unacceptable.
C2A	Only children are included. Justification for exclusion of adults is acceptable.

Note that the three-variable alphanumeric codes presented here are examples. They do not represent the full set of codes used to characterize applications with respect to the inclusion of women and minorities in participant groups.

Designation of Project as a Clinical Trial

Use the following codes to record the view of the SRG as to whether the application in question is consistent with this definition of a clinical trial.

Code	Explanation
Y	Application is consistent with NIH definition of clinical trial.
N	Application is not consistent with NIH definition of clinical trial.

Animal Welfare

Use the following codes to document the views of the SRG regarding the use of live vertebrate animals in research.

Code	Explanation
10	No live vertebrate animals involved.

30 Live vertebrate animals involved.

Verified; no SRG concerns or comments.

The care and involvement of animals is appropriate.

An approved Animal Welfare Assurance is on file with OEP.

A verification of a review by the Institutional Animal Care and Use Committee (IACUC) and approved protocols involving animals dated no earlier than three years before receipt of the application are on file in the office of the SRG.

32 Live vertebrate animals involved.

Verified; SRG comments.

Assurance and verification requirements have been met.

The SRG has approved the proposed involvement of animals, but has comments on their care or involvement.

Or, the project specifies plans to involve animals in the future.

Or, domestic or foreign sites specified in the application (other than the applicant's organization) do not have Animal Welfare Assurances on file with OEP.

44 Live vertebrate animals involved.

Verified; SRG concerns.

Assurance and verification requirements have been met, but the SRG has recommended limitations on the proposed research, has imposed restrictions, or has concerns regarding care and use of animals in the project.

An award will not be made until any problems identified by the SRG have been resolved.

45 Live vertebrate animals involved.

No SRG concerns or comments.

The SRG has approved the proposed involvement of animals, but there is no Animal Welfare Assurance on file with OEP.

47	Live vertebrate animals involved. SRG comments. **Note:** This code refers to the same circumstances as Code 32, except that no Animal Welfare Assurance is on file with OEP
48	Live vertebrate animals involved. No Assurance, SRG concerns. **Note:** This code refers to the same circumstances as Code 44, except that there is no Animal Welfare Assurance on file with OEP.

Coding Multiple Component Applications

Multiple component applications involve several projects or substudies, and the individual projects may involve distinct populations or specimen collections. Codes should be assigned to each component using the coding system specified under Inclusion of Women, Members of Minority Groups, and Children.

In addition, single codes should be assigned to the full application, based on the following criteria.

- **Scientific acceptability of the proposed research.**

Code	Explanation
A	Each project or substudy satisfies at least one of the criteria for scientific acceptability.
U	At least one project or substudy fails to meet the criteria for scientific acceptability.

Appropriateness of the composition of the participant group.

Coding should reflect the collective representation proposed for all projects or substudies, even if some components involve only one gender or include no members of minority groups. For example, in a large clinical trial, substudies may be conducted in several different areas of the United States, including areas where few African-Americans reside. If African-Americans are not included in that substudy, but are included in other substudies in numbers that are proportional to their numbers in the local population, the project should be coded as acceptable in terms of the inclusion of members of minority groups.

Coding Foreign Applications, Applications for Training Grants, and Applications without Multiple Assurances

- The codes used to characterize applications involving only domestic institutions should also be applied to applications from foreign institutions or from domestic institutions with a substantial foreign component. These applications must also meet the same assurance and certification requirements as applications involving only domestic institutions.

- Training grants (T32, T34, and T35) are exempt from coding requirements. However, the terms and conditions of awards specify that any projects to which trainees are assigned must be in compliance with NIH policies on the inclusion of women and members of minority groups in clinical research.

  Specific guidelines are can be obtained from the Policy Office for the Review of Extramural Programs in the NIH Office of the Director.

- Codes for organizations without multiple project assurances.
  Foreign institutions and small businesses (who apply for funds under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) mechanisms) are less likely to have sought and obtained the assurances required for research involving vertebrate animals than are US research universities and other research centers. Thus, in the initial review, applications from these organizations are likely be coded as 45, 47, or 49.

  To receive funding from NCI, however, all organizations must meet the animal welfare requirements. If they file the appropriate documents, new codes can be assigned to their applications and, if their applications obtain favorable priority scores, and meet the special criteria that apply to foreign organizations and small businesses, their applications can be funded. For an official statement of PHS policies regarding the welfare of animals in research, see Manual Issuances 4206 and 6000-3-4.58, or the website at http://www3.od.nih.gov/oma/manualchapters/grants/4206.htm.

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Releasing Codes and Priority Scores

Priority scores and codes are released into IMPAC II no later than three working days after the SRG meeting, and budget information is released within five working days of the meeting.

In disseminating the results of review group meetings, the identity of reviewers must remain confidential. Individual scores assigned by reviewers to particular applications will not be available to non-DEA personnel. If an SRA receives a request for such information, he or she should discuss the request with DEA management for appropriate action.

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Preparing and Releasing Summary Statements

The summary statement is the official record of the recommendations made by peer review groups. Summary statements are based on information from the application, the evaluations of assigned reviewers, the reports from site visits, the opinions of consultants, and the notes made by the SRA and GTA during the SRG meeting.

The summary statement characterizes the proposed research and explains the substantive considerations that led to the specific recommendations made by the SRG. These important documents are used in many ways.

- The National Cancer Advisory Board (NCAB) uses the judgments about the scientific merit of applications presented in summary statements as the basis for their recommendations as to whether applications should be funded.
- NCI staff members use the information presented in summary statements in discussing the outcomes of reviews or Institute actions with applicants, in managing grants, and in preparing program reports.
- Applicants use the information in summary statements as a basis for revising applications prior to resubmission, for improving particular aspects of funded research, and for guidance in shaping their research plans and subsequent applications.
- Congressional or Executive Branch staff members use summary statements in studies of the work of NIH.

This section describes the content and format of summary statements, specifies deadlines for completing them, and procedures for releasing them when they are completed.

Meeting Deadlines for Summary Statements

Immediately following the release of information about priority scores, codes, and budgets for applications reviewed at SRG meetings, SRAs must begin to prepare summary statements. This requirement is essential to ensure that completed summary statements are available before NCAB activities begin.

With a few exceptions to be detailed below, a summary statement is required for each of the applications reviewed at the SRG meeting. Generally they should be completed and entered into IMPAC II within five weeks after the last day of the SRG meeting or four weeks before the National Cancer Advisory Board meets, whichever comes first.

For applications submitted in response to RFAs and PAs, the SRA should contact the PD to determine the order in which summary statements should be prepared.

Variations in the style and format of some summary statements may affect the amount of time required to prepare them. In such cases, SRAs should consult with DEA management to establish deadlines.

Exception I: An application may be deferred because further information is needed before the application can be properly reviewed or because the SRG recommended that a site visit be conducted. If an application is deferred, no summary statement is required. Instead, the SRA writes to the applicant describing the issues that resulted in the deferral or the recommendation to conduct a site visit. A copy of this letter should be kept in the SRG files so that it will be available to the members of a site visit team or to SRG members at their next meeting.

Exception II: If an application from a foreign institution is deferred because the SRG recommended that a site visit be conducted, a complete summary statement must be prepared. Although summary statements will eventually play a role in decisions about awards to these institutions, their first purpose is to help the NCAB determine whether a site visit is needed.

Writing Summary Statements: Correct Format

In general, summary statements must be prepared in a standard format because they will eventually be merged into an electronic database. Some variations, however, may arise as a result of differences in the nature of the application and the outcome of the review.

This section describes the format of summary statements for:

- Nonscored applications subjected to streamlined review.
- Nonscored applications not subjected to streamlined review.
- Investigator-initiated applications for which priority scores were assigned.

Nonscored Applications Subjected to Streamlined Review

Summary statements for applications that were designated as unscored or not recommended for further consideration must contain:

- A standard paragraph about their unscored status.
- The reviewers' critiques.
- Any administrative notes or comments on human subjects issues that may be warranted.

If an unscored application has been discussed, the important points from the discussion should appear in the critiques or in an administrative note written by the SRA.

Nonscored Applications Not Subjected to Streamlined Review

Summary statements for applications that were designated, after discussion, as not recommended for further discussion, or applications designated as not recommended for further discussion in review procedures that do not involve streamlining (e.g., small SEPs or applications submitted under funding mechanisms-such as fellowships-that are exempt from the streamlined review process) should contain:

- A standard paragraph about their unscored status.
- The reviewers' critiques.
- A Review and Summary of Discussion
- Any administrative notes or comments on human subjects issues that may be warranted.

Investigator-initiated Applications That Received Priority Scores

- Resume and Summary of Discussion

This section is based on notes from the SRG meeting. It contains the SRG's assessment of the scientific merit of the project, the priority score assigned to the application, and recommendations regarding the budget and the duration of support. This information should be presented in a single, half-page paragraph.

- Description

  In most cases, the description is taken verbatim from the description of the project presented in the application. In some cases, reviewers will have included descriptive material in their critiques, and this material may be included under the Description heading

- Critique

  The critique section contains the written critiques from each assigned reviewer, and, if available, written comments from the assigned readers. If comments from outside reviewers were presented at the SRG meeting, they should be included in the summary statement. The critiques should be incorporated, essentially unaltered, into the summary statement. Critiques may be edited for grammar and readability, but need not be synthesized. Critiques must be numbered (i.e., Critique 1, Critique 2, and so on), but, to protect the identify of reviewers, these numbers should not be connected to the assigned role (i.e., primary, secondary, tertiary) of reviewers.

- Resources and Environment

  Separate comments on research resources and the research environment are necessary only if there are unusual or noteworthy aspects of the facilities or of departmental or interdepartmental cooperation.

- Gender and Minority Subjects

  This section should characterize the comments of the SRG with regard to the composition of the participant group. If the SRG noted concerns about the inclusion of women or members of minority groups, these concerns should be reported in an Administrative Note

- Budget

  The budget narrative should indicate whether the budget is appropriate given the nature and purpose of the research. If reductions or increases in the budget are recommended, the changes should be itemized and specific reasons for each change should be presented.

- Human Subjects and Animal Welfare

  This topic need only be included if the SRG has specified comments or concerns about human subjects or animal welfare.

- Biohazards

  This topic need only be included if the SRG has specified comments or concerns about the production or use of materials that may constitute biohazards.

- Special Notes

Special aspects of an application or its review must be indicated at the top of the summary statement, preceding the Resume and Summary of Discussion.

Including Special Notes

In certain cases, the information presented in the standard format described under Writing Summary Statements: Correct Format must be supplemented by special notes about an application or its review.

If the research proposed contains features that require the use of special notes, these notes should be presented at the top of the summary statement, preceding the Resume and Summary of Discussion. In most cases, these special notes must be accompanied by a paragraph explaining the reason for the note. These paragraphs should appear at the bottom of the summary statement.

In other circumstances, a paragraph at the end of the summary statement may be required to explain codes assigned to the application, or other special features that may be relevant to administrative decisions following the review.

In the list of special notes and their related paragraphs below:

- Items marked by an asterisk must be included at the top of the summary statement.
- Items not marked by an asterisk may be discussed in paragraphs following the summary statement.

List of Special Notes

- Revision*

  A revised summary statement must contain a statement about the nature and date of the revision. The word REVISED and the date of the revision must appear in the first line following the budget recommendation in the computer-based template used for summary statements.

- Administrative Note*

  The SRA may use an administrative note to clarify topics not related to scientific merit. Such topics might include concerns about policy, budgetary overlap, or duplication of grants. The SRA may include the views of the SRG as to how these matters might be handled by NCI staff.

- Foreign*

  A paragraph under the heading Criteria for Foreign Award must appear after the last critique. The paragraph should comment on the availability of special opportunities, investigators or facilities. This paragraph is not required for applications that include a foreign component, but are submitted by domestic institutions.

- Use of Fetal Tissue*

  Include a sentence indicating that the application proposes the use of human fetal tissue.

- Use of Human Embryonic Stem Cells*

Include a sentence indicating that the application proposes the use of human embryonic stem cells.

- High Risk/High Impact*

  If an application is identified as high risk/high impact, an explanation for this characterization should be presented at the end of the summary statement.

- Split Vote of the Review Committee*

  If split votes are obtained in response to motions to designate an application as Not Recommended for Further Consideration or Deferred for Further Information, the votes of the SRG must be reported on the face page of the summary statement. Votes should be recorded in the following format:

  ___Number of votes for the recommendation to not recommend or to defer.
  ___Number of votes against the motion.
  ___Number of abstentions from the vote.
  ___Number of reviewers who assigned a score. Minority opinion included.

- Outside Opinion Obtained

  If outside expertise was sought for the review of the application, the preceding phrase must appear at the top of the summary statement, but no explanatory paragraph is required.

- Minority Opinion

  If two or more members of the SRG voted against the majority in a motion as to whether the application should be designated as Not Recommended for Further Consideration and the motion passes, the minority opinion must be reproduced in the summary statement. If only one member disagrees with the recommendation of the majority, a brief statement explaining the reason for the disagreement may be incorporated in the Resume and Summary of Discussion section of the summary statement.

- Inclusion of Women, Members of Minority Groups, and Children

  If the research plan is coded as unacceptable with regard to the inclusion of women, members or minority groups or children, reasons for that assessment must be presented unless the application has been designated as Not Recommended for Further Consideration.

- Human Subjects Concerns

  Codes reflecting the view of the SRG with regard to the plan for the protection of human subjects are always presented at the top of the summary statement. When the SRG has human subjects concerns (coded 44 or 49), the SRA must include a paragraph labeled Human Subjects Concerns at the end of the summary statement. This paragraph must specify potential or actual risks identified by the SRG or restrictions recommended by the SRG.

  This paragraph should be included only when the concern reflects a consensus within the SRG as expressed in response to a query from the chairperson. If only one or two reviewers express concerns about human subjects issues, these concerns should be included in their critiques and indicated in the code assigned by the reviewer.

- Animal Welfare Comments and Concerns

  Codes reflecting the view of the SRG with regard to the plan for the use and care of animals are always presented at the top of the summary statement. When the SRG has comments (coded 32 or 47) or concerns (coded 44 or 49), the SRA must include a paragraph labeled Animal Welfare Comments or Concerns. This paragraph must specify potential or actual risks identified by the SRG or restrictions recommended by the SRG.

  This paragraph should be included only when the concern reflects a consensus within the SRG as expressed in response to a query from the chairperson. If only one or two reviewers express concerns about the welfare of animals, these concerns should be included in their critiques and indicated in the code assigned by the reviewer.

- Biohazard

  If the research plan specifies the use of potentially hazardous materials or procedures, a paragraph noting these facts, as well as any concerns on this topic reported by members of the SRG, should be included at the end of the summary statement.

Identifying Members of the SRG: The Roster

A list of participants in the SRG must be included in each summary statement. Single asterisks should be used to identify temporary members. In addition to names of members of the SRG, the roster should specify their degrees, their institutional affiliation, and their mailing address.

In the section of the summary statement that includes the roster, a footnote must be included to indicate that consultants were required to leave the room during the discussion of any application for which their presence would constitute or might have appeared to constitute a conflict of interest.

Releasing Summary Statements

Summary statements are to be released into IMPAC II within three or four weeks of the meeting of the SRG. After releasing the summary statements, the SRA must:

1. Send email to the PD indicating that the summary statements have been released.

2. Send summary statements for unscored applications, along with the unedited critiques, to applicants.

3. Send summary statements for scored applications to the PD.

4. Send copies of any application coded 44, 47, or 49, along with the summary statement for each application, to OEP.

   These applications must be sent to OEP even if they were not scored.

5. Send a copy of any application involving chimpanzees as experimental animals, along with the summary

statement, to DEA.

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Creating and Retaining Records of SRG Meetings

To comply with legal requirements regarding the proceedings of chartered review groups, reports of SRG meetings must be prepared and retained in appropriate NIH offices.

Documenting SRG Meetings (FACA Requirements)

The Federal Committee Advisory Act (FACA) specifies that transcripts, meeting summaries, and any other documents related to meetings of chartered review groups (which includes SRGs) must be made available for public inspection and copying. Access to these records is governed by the FACA, the Freedom on Information Act, the Privacy Act, and Department of Health and Human Services regulations.

To comply with this requirement:

1. The GTA prepares a meeting summary.
2. The lead GTA approves the summary.
3. The SRA reviews and signs the summary.
4. The GTA sends the summary, along with a copy of the roster, to CMO.

Retaining Records of SRG Meetings

The SRG office must retain:

- The original copy of the meeting summary for three years.
- Administrative materials, such as conflict of interest statements, for seven years.
- Current and recent (up to three years) summary statement books.

  Older summary statements are filed electronically by NIH.

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Managing Post-Review Communications with Applicants

The PD sends the summary statements, along with a letter of transmission, to the applicant. Applicants should be encouraged to call the PD to discuss the summary statement.

Being certain to adhere to NIH rules regarding the confidentiality of the review process, PDs may freely discuss the outcome of the review process with applicants. For instances in which it can be inferred that reviewers are not in complete agreement, the PD must advise the applicant to consider the Resume and Summary of Discussion contained in the summary statement as the "take home message" from the peer review process. PDs may rely on the SRA's notes from the SRG meetings in discussing the results of the review process with applicants.

In discussing the details of the proposed research, PDs may recommend changes that could be incorporated into an amended application, but should clearly indicate that these discussions are advisory. PDs must take care to ensure that that their recommendations are not interpreted as predictions about the outcome of the review of an amended application and that their recommendations do not imply that amended applications, even if positively reviewed by the SRG, will be funded.

Applicants should be advised that, in submitting an amended application, they must respond to the specific problems noted by the SRG and that, if they disagree with the assessments of the SRG, they must present their views in the amended application.

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The Appeals Process

Reasons for Appeals

An applicant who believes that his or her application was misjudged by members of the SRG may file an appeal. There are two different reasons for appeals:

- The applicant may believe that there were procedural flaws in reviewers' assessments of the scientific merit of the application.

- The applicant may disagree with the reviewers' recommendations for the project budget or period of award.

NCI funding decisions may not be appealed.

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Responding to Appeals of Assessments of Scientific Merit

Differences of opinion between an applicant and the members of the SRG cannot be used as the basis for an appeal. To contest the SRG's assessment of the scientific merit of an application, the applicant must identify flaws in the review procedure. Such concerns may arise if an applicant believes that the outcome of the review was affected by:

- Bias

  A review is considered to be biased if a reviewer states that an entire area of research is unimportant

- Conflict of interest.

  A conflict of interest exists if the professional or financial interests of a member of the SRG, or the institution with which the member is affiliated, interfere with the member's ability to assess an application objectively. The applicant must be able to specify the nature of the conflict.

- Lack of appropriate expertise within the SRG

  The SRG may be judged to lack appropriate expertise if the group does not include individuals with substantial knowledge of the research topic and the research methods presented in the application.

- Factual errors

  The SRG may be judged to have made factual errors if evidence or assessments presented in the reviews are clearly incorrect.

Discussing Appeals with Applicants

In most cases, applicants who are considering whether to file an appeal will consult with PDs. **PDs must tell the applicant that an amended application may not be filed while an appeal is pending.**

In addition, PDs should carefully review the distinction between a difference of opinion and a procedural inequity, and should discuss the relative merits of filing an appeal as opposed to submitting an amended application.

PDs may wish to present evidence as to the likelihood of obtaining funding based on an amended application compared to the likelihood of obtaining a favorable decision in response to an appeal.

The decision as to whether to appeal the recommendation rests, however, with the applicant.

Acknowledging Appeals

If the applicant decides to file an appeal, the PD must:

1. Tell the applicant to send a formal letter by US Mail specifying the alleged flaw.

   Applicants may submit appeals during the period from the release of the summary statement up to 30 calendar days after the next meeting of the National Cancer Advisory Board (NCAB). If the applicant submits the appeal before the NCAB meeting, notice of the appeal and a report of what has been done to resolve the appeal must be submitted to the Board along with the summary statement.

2. Acknowledge receipt of the appeal within 10 working days in a letter sent by US Mail.

   The letter must specify that the applicant will be notified of the final decision within 30 working days after either the NCAB meeting or the date the letter was received (if the appeal arrives too late to presented at the NCAB meeting), whichever is later.

Assessing the Merits of Appeals (PDs and SRAs)

After acknowledging the applicant's letter, the PD must send a copy of both letters (the applicant's appeal and the PD's reply) to the SRA who managed the initial review.

After receiving these letters, the SRA may attempt to clarify reviewers' comments by consulting members of the SRG or may respond directly to the PD. The PD and the SRA must then confer to assess the merits of the applicant's appeal.

There are three possible outcomes of this discussion.

- The PD and the SRA agree that re-review is warranted.
- The PD and the SRA agree that re-review is unwarranted.
- The PD and the SRA disagree as to whether re-review is warranted.

The procedures for processing appeals under each of these conditions are described the sections below.

PD and SRA Agree that Re-review Is Warranted

If the PD and the SRA agree that re-review is warranted, the PD informs the applicant of the decision to recommend re-review. The applicant may then resubmit the unamended application. The unamended application will be reviewed without reference to the previous review by an SRG, which may be the same SRG that conducted the initial review or a different one.

The PD must submit all correspondence associated with the review and the appeal to the Division of Extramural Activities (DEA). DEA then submits copies of this correspondence to the Special Actions Subcommittee of the NCAB.

After the meeting of the National Cancer Advisory Board (NCAB), the PD must send all documents related to the appeal to the Grants Administration Branch (GAB), where they will be maintained in the official file.

PD and SRA Agree that Re-review Is Unwarranted

If the PD and the SRA agree that re-review is unwarranted, the PD informs the applicant of this decision in a letter sent by US Mail.

If the applicant decides not to pursue the appeal, no further administrative action is required.

The correspondence concerning the appeal must be attached to the summary statement regarding the application that is sent to the NCAB, along with a note indicating that the issue that prompted the appeal has been resolved.

If the applicant decides to pursue the appeal, the PD must send copies of the documents associated with the appeal to the NCI Appeals Officer in DEA. These documents include:

- The Routing and Transmittal Form: Appeal.
- The applicant's appeal letter.
- The summary statement from the original review.
- Recommendations from the SRA and the PD.
- Written comments from the SRA and, if available, the SRG.

The Appeals Officer transmits these documents to the Special Actions Subcommittee of the NCAB. The Board then determines whether to reject the appeal or recommend that the application be re-reviewed.

If the NCAB rejects the appeal, no further action is required. NCAB decisions about appeals based on assessments of scientific merit can not be appealed.

If the NCAB recommends that the application be re-reviewed, reviewers examine the unamended application without reference to the previous review. The NCAB may recommend that the re-review be conducted by a SEP or by an alternate SRG.

After the NCAB meeting, the PD must:

1. Notify the applicant of the NCAB decision in a letter sent by US Mail

2. Send all documents related to the appeal to GAB, where they will be retained in the official file.

PD and SRA Disagree as to Whether Re-review Is Warranted

If the PD and the SRA disagree as to whether re-review is warranted, the PD informs the applicant that the merits of the appeal will be determined by the NCAB. The PD must send copies of the documents associated with the appeal to the NCI Appeals Officer. These documents include:

- The Routing and Transmittal Form:Appeal.
- The applicant's appeal letter.
- The summary statement.
- Recommendations from the SRA and PD.
- Written comments from the SRA and, if available, the SRG.

The Appeals Officer transmits the appeal letter to the Special Actions Subcommittee of the NCAB, along with comments from the PD and the SRA. The Board then determines whether to reject the appeal or recommend that the application be re-reviewed.

If the NCAB rejects the appeal, no further action is required. NCAB decisions about appeals based on assessments of scientific merit can not be appealed. If the NCAB recommends that re-review is warranted, reviewers examine the unamended application without reference to the previous review. The NCAB may recommend that the re-review be conducted by a SEP or by an alternate SRG.

After the NCAB meeting, the PD must:

3. Notify the applicant of the NCAB decision in a letter sent by US Mail.

4. Send all documents related to the appeal to GAB, where they will be retained in the official file.

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Responding to Appeals for Restoration of Time or Budget

During the review process, the SRG may recommend that the proposed budget and period of award be reduced. Applicants who believe that such reductions would compromise their ability to perform the proposed work may appeal for restoration of time or budget.

In general, applicants who wish to appeal budget recommendations must do so before Institute funding decisions have been made.

Acknowledging Appeals

If the applicant decides to file an appeal, the PD must:

1. Tell the applicant to send a formal letter by US Mail justifying the request to restore time or budget.

   Applicants may submit appeals during the period from the release of the summary statement up to 30 calendar days after the next meeting of the NCAB. If the applicant submits the appeal before the NCAB meeting, notice of the appeal and a report of what has been done to resolve the appeal must be submitted to the Board along with the summary statement.

2. Acknowledge receipt of the appeal within 10 working days in a letter sent by US Mail.

   The letter must specify that the applicant will be notified of the final decision within 30 working days after either the NCAB meeting or the date the letter was received (if the appeal arrives too late to presented at the NCAB meeting), whichever is later.

Assessing the Merit of Appeals

The PD may, at his or her discretion, recommend adjustments in budget or period of award.

The funds to restore the amount deleted from the project budget will come from the research project grant (RPG) pool. The level of approval required is specified in the Levels of Authority document, which is available at http://camp.nci.nih.gov/admin/grants/10aindex.htm.

The restoration of funds should be processed as a ***Supplement to Award***. In the case of RFAs, the restoration will be drawn from the source of the original funding for the RFA.

If the project budget is restored, the Notice of Grant Award can serve as official notification. If the request to restore the budget is rejected, the PD must notify the applicant of this decision in a letter sent by US Mail.

All documents related to the appeal must be sent to the DEA, which will transmit the information to the Special Actions Subcommittee of the NCAB. In addition, copies of all documents associated with the appeal must be sent to GAB.

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Making Funding Decisions

Shannon Awards

New Investigator Awards (*R01s)

Funding Mechanisms with No Payline (R24/U24 and R13)

Co-Funding Applications

Roles and Responsibilities in Co-Funding Agreements

Co-Funding with NCI as the Primary Assignment

Co-Funding with NCI as the Secondary Assignment

Transferring Applications from Another Institute or Center

Moving Applications from Review to Approval

The process through which applications progress from review to approval for funding depends on several factors. These factors include:

- The funding mechanism under which the application was submitted or to which it is assigned.
- The research priorities specified in the NCI funding plan.
- Where the application falls with respect to the NCI payline.
- The priority score assigned to the application in the peer review process.

The process by which priority scores are assigned is described in Voting on Applications.

Funding Categories and Funding Mechanisms

The NCI budget specifies expenditures in nine funding categories, six of which involve issuing grants to support research or to support activities related to research (e.g., training, construction of research facilities). Each year, about 65% of the NCI budget is used for grants to support these activities.

A funding mechanism is a particular kind of grant. Funding mechanisms vary in terms of the kind of work they

support, eligibility criteria, the size of the grant that can be issued, review procedures, and the procedures used to determine whether grants will be awarded.

The six funding categories and the funding mechanisms within each category are:

- Construction (C06).

  Construction grants support the creation of state-of-the-art cancer research laboratories and clinics for basic and applied research.

- Training (F31-F36 & T32/T35/T36).

  The National Research Service Awards (NRSAs) provide long-term, stable support for the training of scientists and research clinicians.

- Cancer prevention and control.

  The Office of the Director (OD), the Division of Cancer Control and Population Sciences (DCCPS), and the Division of Cancer Prevention (DCP) support research on methods of cancer prevention through grants, contracts, and in-house research.

- Cancer Centers (P30/P20/U54) and Specialized Programs of Research Excellence (SPORE) (P50).

  Funds for cancer centers and SPOREs support diverse research approaches to the problem of cancer, incorporating all applicable disciplines.

- Research project grants (RPGs).

  RPGs are awards given in response to investigator-initiated applications for research funds. Most grants issued by NCI are RPGs; expenditures for these grants constitute 45-50% of the NCI budget.

  The specific kinds of RPGs are:

  - Traditional (R01)

  - Program Projects (P01)

  - MERIT Awards (R37)

  - RFAs (R01, U01)

  - Cooperative Agreements (U01 not responsive to RFA)

  - Shannon Awards (R55)

  - Small Grants (R03)

  - Exploratory/Developmental Grants (R21/R33)

- SBIR/STTR Grants (R43/R44 & R41/R42)

- Other research grants (non-RPGs).

  This category includes the Research Career Program and other special programs. They include:

  - Career Program

    - RCDA (K04)

    - Clinical Oncology (K12)

    - Physician Investigator (K11)

    - Preventive Oncology (K07)

    - Clinical Investigator (K08)

    - Temin Awards (K01)

  - Cancer Education Program (R25)

  - Clinical Cooperative Groups (U10)

  - Scientific Evaluation (U09)

  - Resource Grants (R24/U24)

  - Conference Grants (R13)

  - Exploratory Grants/Cooperative Agreements (U56)

  Through the Comprehensive Minority Biomedical Program (506), applicants may seek any RPG or non-RPG grant.

Assigning Applications to New Funding Mechanisms

An application submitted under one funding mechanism may, during the funding process, be assigned to another.

Typically, such reassignments occur when an application not funded under one mechanism is assigned to another. For instance, an investigator-initiated application not funded as an R01 may be funded as a Shannon Award.

Or, if the research plan presented in an unsolicited application indicates that NCI staff will play a substantial role in the proposed work, the award may be converted from a grant to a cooperative agreement. In such cases, grants

funded under the R01 mechanism would be converted to U01s, and grants funded under the P01 mechanism would be converted to U19s. For more information about this process, see Converting Grants to Cooperative Agreements.

The NCI Funding Plan and Payline

Each year, the NCI Executive Committee (EC), which is made up of the Director of NCI and NCI Division Directors, develops NCI's **funding plan** and specifies the **payline**.

- The **funding plan** is a set of priorities for research project grants (RPGs).

  In developing the funding plan, the EC determines how to allocate NCI extramural research funds to achieve scientific goals.

- The **payline** is a cut-off point.

  The level of the payline is determined by the NCI budget and its funding plan. Applications with priority scores or percentiles within the payline are likely to be funded. Applications with priority scores beyond the payline are not likely to be funded.

The funding plan and the payline for the coming fiscal year are established after an appropriation is signed into law–usually in October–but may be revised subsequently in response to changes in the budget, changes in research priorities or the quality of grants submitted during a particular round of submissions.

For information about current paylines, see http://camp.nci.nih.gov/admin/oem/efdb/paylines-fy01.html.

Funding decisions with regard to applications submitted in response to RFAs are based on the development of a funding plan that is specific to the initiative. For information about how applications submitted in response to RFAs are selected for funding see, Selecting Applications for Funding: Applications Submitted in Response to NCI Initiatives.

For information about other mechanisms that do not involve a payline, see Funding Mechanisms with No Payline.

Skipping Applications

After the peer review process–whether for investigator-initiated applications or applications submitted in response to NCI initiatives–a ranking list of approved applications, ordered by priority scores, is created. In most instances, applications are selected for funding in the order of their appearance on the ranking list.

In some cases, however, applications may be skipped for programmatic or budgetary reasons. For instance, if it is determined that the there is substantial scientific overlap between an application being considered for funding and an already funded project, skipping the newer application may be warranted. Skips must be approved by the branch chief and the division director.

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IMPAC II: Technology for Administering Grants

IMPAC II is an electronic database that is used to track applications as they move through the funding process.

After the peer review process, DEA sends PDs a paylist, which is a list of all the applications assigned to their program areas that fall within the payline. PDs must enter identifying information about each of these applications into IMPAC II. This record then becomes the repository of all information about an application as it moves through the approval process.

Applications with priority scores that fall outside the payline are entered into IMPAC II as determinations are made about whether to fund them through procedures other than the expedited funding process or the regular process.

Several computer applications have been designed to track funding decisions in the IMPAC II database. Collectively, these applications are known as the Grants Reporting and Information Tracking System (GRITS).

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Making Funding Decisions

After applications have been reviewed, NCI staff must decide which applications to fund and how to fund them. Because funding decisions involve these two determinations, they are not straightforward, dichotomous "yea or nay" choices. Instead, the funding process should be seen as contingent and iterative.

- The funding process is contingent in that whether and how applications will be funded depends on several factors.

  Most obviously, funding decisions depend on the priority score assigned to the application in the peer review process, but other factors also enter into the process. For instance, some funding decisions are based, at least in part, on characteristics of the applicant. One must be a distinguished senior investigator to be considered for a MERIT award, and one must be a new investigator to be considered for a *R01 award.

- The funding process is iterative in that applications not funded in an initial pass through the funding process may be reconsidered for funding through another process.

  For instance, an unamended investigator-initiated application whose priority score falls outside the payline established for funding applications for the regular process (but within specified limits) may be considered for funding through the accelerated executive review process.

Operating effectively in the grant-making arena requires understanding the processes, and the relationship between those processes, through which funding decisions are made.

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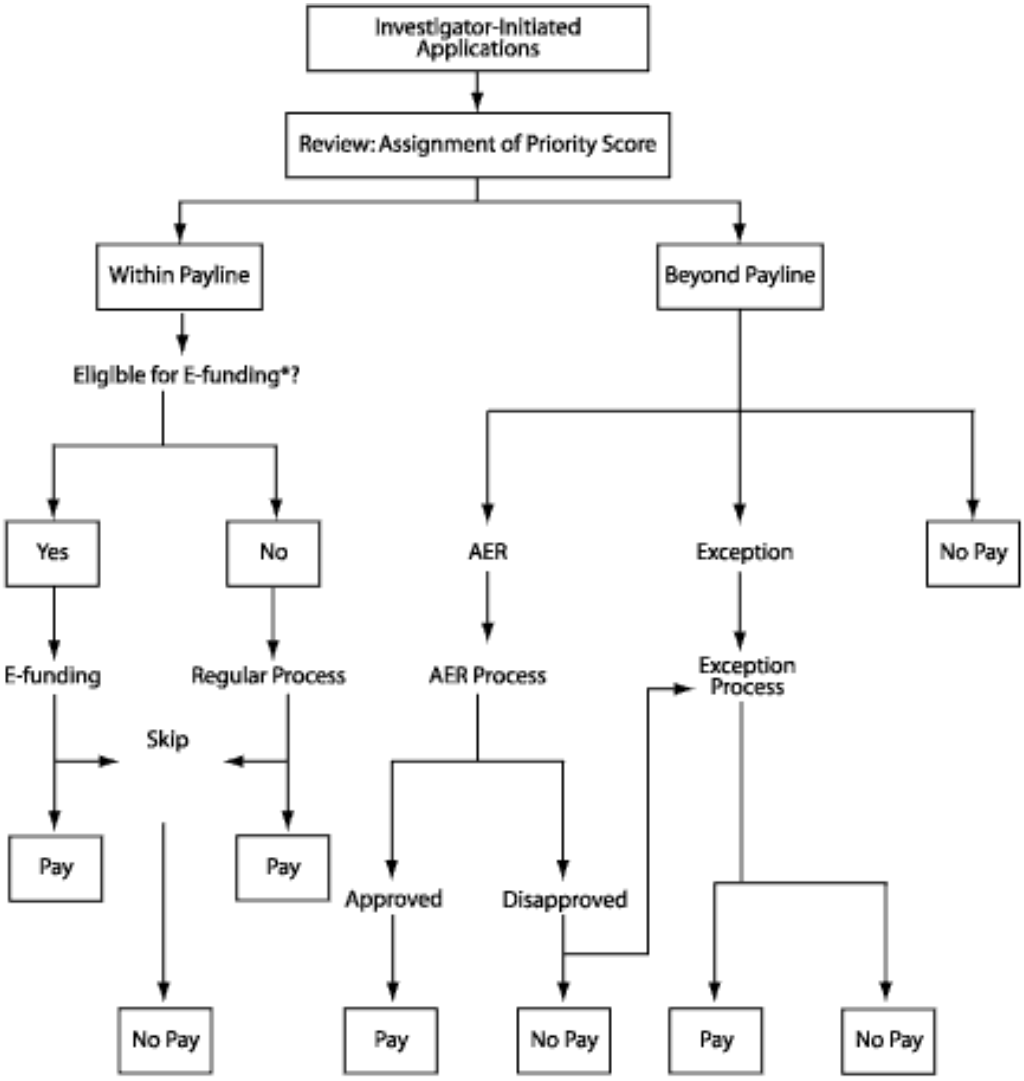
Funding Processes

Figure 1 shows how investigator-initiated applications move into and through the funding process, This diagrams illustrates the contingent, iterative character of funding decisions.

The outcome of initial funding decisions depends, first, on whether the application falls within the payline. If the priority score assigned to the application is such that it falls beyond the payline it can enter a new round of decision-making where it is again considered for funding.

For investigator-initiated applications, there are two alternative procedures through which an application might be funded—the accelerated executive review process and the exception process—as well as several special kinds of awards.

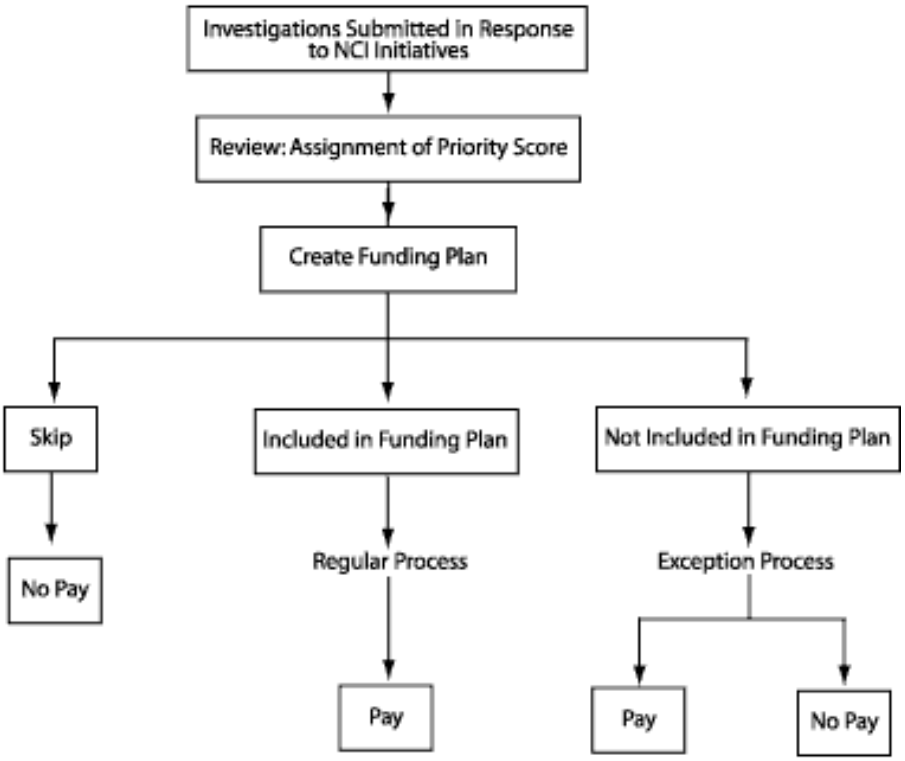
Figure 1. Funding Decision Processes: Investigator-Initiated Applications



*Expedited Board concurrence and early approval

Figure 2 shows how applications submitted in response to NCI initiatives move into and through the funding process. Funding decisions are based on priority scores, type of research proposed, and available funding. If the application is not funded through the regular process, it may be considered for funding through the exception process.

Figure 2. Funding Decision Processes: Applications Submitted in Response to NCI Initiatives



For investigator-initiated applications, the most frequently used funding processes are:

- The expedited Board concurrence and early award process (known as the expedited process).
- The regular process.
- The accelerated executive review process
- The exceptions process.

For applications submitted in response to NCI initiatives, the two most frequently used funding processes are:

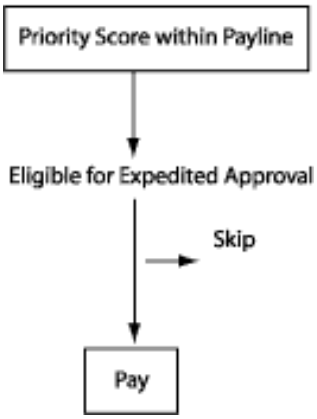
- The regular process.
- The exceptions process

Further, both investigator-initiated applications and applications submitted in response to NCI initiatives may be funded through:

- The end-of-year funding process.

Each of these processes is explained in the following section.

The Expedited Approval Process



Certain applications whose priority scores fall within the payline may be eligible for funding through the expedited NCAB approval process. Eligibility requirements are specified in the section below.

For budgetary or programmatic reasons, it may be necessary or desirable to skip applications whose priority scores are within the payline. Any skips must be justified in the I2E database.

Awards issued through the expedited approval process can generally be paid 3-5 months sooner than awards issued through the regular process.

In most cases, the NCAB must approve applications for funding. NCAB approval for applications funded through the expedited Board concurrence and early approval process (i.e., the expedited process) is obtained electronically, rather than by presenting applications for approval at an NCAB meeting. Using the expedited approval process, awards can be issued in 7-9 months of submission, rather than in 10-12 months as is the case for applications funded through the regular process.

This section describes:

- The kinds of grants that are eligible for expedited approval.
- The process of selecting applications for funding.
- The process of creating the paylist.

Eligibility Requirements for the Expedited Process

The expedited approval process may be used to fund:

- Unsolicited Type 1 and Type 2 R01s.
- Exploratory/Developmental Grants (R21).
- Small Grants, i.e., grants for less than $50, 000 in direct costs issued under the R03 mechanism

The expedited process may not be used to fund:

- Foreign applications or domestic applications with a foreign component.
- Applications for which the SRG identified concerns about the protection of human subjects, the welfare of laboratory animals, or biohazards.

These applications must be called to the attention of the NCAB. For information about processing foreign grants and applications about which members of the SRG expressed concerns, see Processing Foreign Applications and Identifying Applications That Must Be Reported to the NCAB.

Selecting Applications for Funding through the Expedited Process

After receiving the list of eligible applications from DEA, the PD must:

1. Identify applications that are not eligible for the expedited funding process.
2. Select applications for funding.

   In most instances, applications are selected in straight priority score order. However, PDs may skip applications that already receive support from other sources, or for other programmatic reasons.

Creating the Paylist for Expedited Funding

For each application that falls within the payline, the PD must:

1. Indicate whether the application has been selected for pay.

   Using the GRITS paylist module, select "Yes" or "No" under "Intent to Pay." If the application is not selected for pay (i.e., is skipped), use the drop-down menu under "Comments" to enter the reason for the exclusion.

   Skips must be justified in the GRITS form. To learn which NCI official must approve skips, see the Grants Administration Branch (GAB) Levels of Authority document at http://camp.nci.nih.gov/admin/grants/loaindex.htm.

2. Assign basic and applied research (B/A) codes, designate applications that are AIDS-related, and assign patient-oriented research (POR) codes.

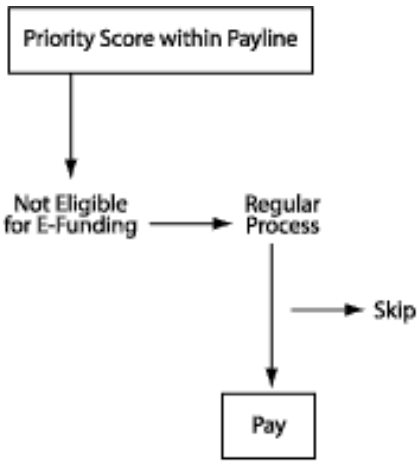
3. Obtain updated information about other support from the applicant.

4. Fill in the green sheet, which is required to authorize GAB to pay the grant.

5. Send the application and the green sheet to GAB.

For information about updating an applicant's other support and the steps required to complete the green sheet, see Completing Green Sheets.

The Regular Process



The regular process is used for applications submitted in response to NCI initiatives, for applications submitted under the P01, P30, P50/P20 mechanism, for foreign applications and for applications that involve concerns raised by the SRG.

In some cases, it may be necessary or desirable to skip eligible applications. To determine when it is appropriate to skip an application, see The Skip Process.

The regular process is used to fund both investigator-initiated applications and applications for grants or cooperative agreements submitted in response to NCI initiatives. However, the procedures for creating a list of to-be-funded applications that has been approved by senior NCI staff depend on whether the application was initiated by the investigator or submitted in response to an NCI initiative. Thus, they are discussed separately below.

Selecting Applications for Funding: Investigator-Initiated Applications

After receiving the paylist of eligible applications from EFDB, the PD must select applications for funding.

In most instances, applications are selected in straight priority score order. However, PDs may skip applications that already receive support from other sources or for other programmatic reasons.

Selecting Applications for Funding: Applications Submitted in Response to NCI Initiatives

Applications for grants and cooperative agreements submitted in response to NCI initiatives are reviewed by ad hoc groups of NCI peer reviewers. The group reviews the applications, assigns priority scores, and specifies

budget recommendations.

After these deliberations, PDs devise a **funding plan** based on priority scores and on the amount of money set aside to pay applications submitted in response to the initiative.

In most cases, applications are paid based on priority scores until the funds set aside for the initiative are exhausted.

There are, however, some alternatives to this procedure. NCI staff may decide to:

- Pay none of the grants because all applications received poor priority scores.
- Pay grants based on a sliding scale.

  Grants with top priority scores would receive full funding, and grants with lower priority scores would receive a percentage of the recommended amount. This strategy may be used when the budgets for applications that received high priority scores exceed the amount of money available under the initiative.
- Skip certain applications whose priority scores are within the payline.
- Set the payline at or near an application to be skipped and fund applications with lower priority scores as exceptions.

The completed funding plan must then be reviewed by the division director. Grants are not awarded until after they have been approved by the NCAB.

Creating a Paylist for Funding through the Regular Process

For each application that falls within the payline, the PD must:

1. Indicate whether the application is being selected for pay.
2. Assign basic and applied research (B/A) codes, designate applications that are AIDS-related, and assign patient-oriented research (POR) codes.
3. Indicate whether the application is to be skipped.

   Skips must be justified in the GRITS form. To learn which NCI official must approve skips, see the GAB Levels of Authority document at http://camp.nci.nih.gov/admin/grants/loaindex.htm.

Obtaining Approval of the Paylist for Applications Funded through the Regular Process

The approval process consists of these steps:

1. The branch chief recommends the paylist (created in GRITS by the PD) for approval by the division approving official (DAO), which is usually the division director.

2. After the branch chief approves the paylist, the system automatically generates email to the DAO indicating that the paylist is ready for division approval.

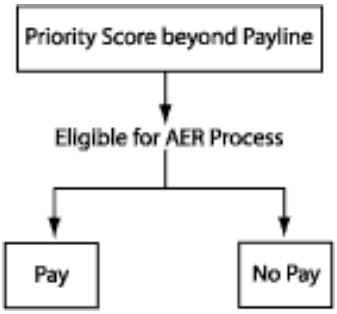
3. For RPGs, financial analysts certify that funds are available to pay the grants and send the approved paylist to GAB. For NRSAs, CORE/SPORE and other non-standard grant programs, the Extramural Financial Data Branch (EFDB) certifies that funds are available to pay the grants. For RFAs and other division-controlled programs, the ARC manager may certify that funds are available.

4. The PD completes a green sheet for each grant that is approved for funding on the paylist.

   Note that completing the green sheet will likely require obtaining information about other support from the investigator, and may involve discussions on other topics as well. For information about the steps required to complete the green sheet, see Completing Green Sheets.

5. GAB approves the paylist.

The Accelerated Executive Review (AER) Process



The accelerated executive review (AER) process may be used to fund applications whose priority scores are just beyond the payline.

The accelerated executive review (AER) process may be used to fund applications whose priority scores are just beyond the payline. Unamended investigator-initiated applications may be considered for awards through this process if they:

- Propose basic research and received priority scores that are no more than five percentage points beyond the payline in the peer review process.

- Propose patient-oriented research and received priority scores that are no more than ten percentage points beyond the payline.

Note that the policy establishing the number of percentage points that defines eligibility for accelerated executive review is established by the Executive Committee and may be adjusted each year.

This process requires that the applicant submit an abbreviated response to the critiques of peer reviewers. This response is reviewed by program staff and, finally, by the NCI Executive Committee.

Selecting Applications for Funding through the AER Process

To fund applications through the AER process, the PD must:

1. Contact the applicant, explain the AER process, and invite him or her to submit an AER request.

   A sample letter containing instructions for the applicant, is available at http://deaintranet.nci.nih.gov/.

   Follow-up discussions by telephone or email are both permissible and desirable. The PD should advise the applicant as to how the request might be made more competitive.

2. Determine whether to recommend that the AER request be funded and prepare a GRITS form to communicate this judgment to the EC.

3. Submit the AER request to the branch chief and division director, along with a written recommendation indicating whether the application should be funded.

Obtaining Approval to Fund an Application through the AER Processs

In determining whether to recommend the grant for funding:

1. The branch chief and division director evaluate the application. If they approve the application for funding, it is forwarded, along with the PD's written recommendation, through the division director to the Executive Committee.

2. The Executive Committee decides whether to fund the application.

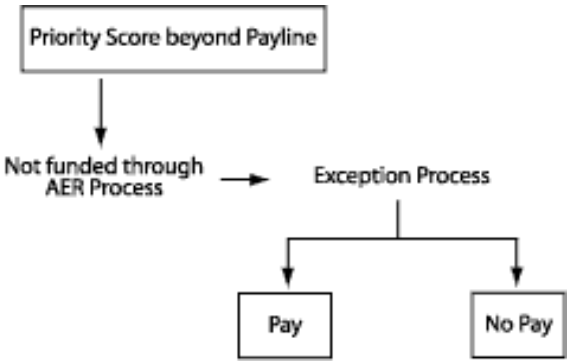
   If the Executive Committee decides to fund the application, the approval form is forwarded to EFDB and GAB and an informational copy is sent to the PD.

   Note that completing the green sheet will likely require obtaining information about other support from the investigator, and may involve discussions on other topics as well. For information about filling in green sheets, see Completing Green Sheets.

   If the Executive Committee decides not to fund the application, it is returned to the PD. The PD then notifies the applicant—by telephone, email or US Mail—that the application will not be funded through the AER process. The PD must inform the applicant that a negative funding decision does not preclude submitting a revised application through normal channels.

PDs may submit applications that were not funded through the AER process for funding under the exception process.

The Exception Process



The exception process is used to fund applications whose priority scores were beyond the payline and not funded through the accelerated executive review process. It is also used to process applications submitted under or assigned to other special funding mechanisms.

Several times each year, NCI staff meet with their division directors to consider applications for funding through the exception process. Through this process, NCI allocates funds to:

- Fund investigator-initiated applications that have not received funding through either the regular process or the AER process.
- Fund applications submitted in response to NCI initiatives that received priority scores outside the payline or to fund applications that were not funded after the initial review because the funds set aside for the initiative were exhausted.

Under EC policies, certain kinds of applications are given high priorities in the exception process. These priorities include:

- Support for research in certain disease areas (e.g., AIDS-related malignancies and breast, ovarian, prostate, head and neck, and brain cancers).

- Supporting for research that aims to address health disparities.
- Supporting applications submitted in response to PAs or RFAs for which no set-aside funds were available.
- Support for new investigators.

The exceptions process is also used to:

- Fund applications submitted under mechanisms that do not involve a payline or funding plan, e.g., the R/U 24 and R13 mechanisms. See Funding Mechanisms with No Payline.
- Restore funds in instances where project budgets were cut in previous decision processes. See Responding to Appeals.
- Provide administrative supplements for unanticipated expenses that arise during the life of a grant. See Administrative Supplements.
- Provide interim support for previously-funded applicants to insure that significant research continues while the applicant competes for new funding. See Interim Support.
- Provide phase-out support when investigators need additional time and resources to finish an already-funded project. See Phase-Out Support.
- Provide small grants to support activities (e.g., collecting feasibility data) that would permit investigators to compete successfully for funds issued through the regular process. See Shannon Awards.

Procedures and timetables for considering awards to be issued through the exceptions process vary across NCI divisions. For information about the exception process within a particular division, see the relevant section below.

DCB Exception Process

In the Division of Cancer Biology (DCB), three two-day exceptions meetings are held each year. To prepare for exceptions meetings, staff members within the branches discuss applications whose priority scores were beyond the payline and decide which applications to put forward for funding.

One week before the meeting, staff members begin to assemble the information required to review the applications put forward for exception funding. To assemble this information:

1. PDs send summary statements for applications proposed for exception funding and draft versions of the exceptions form to the Special Assistant to the Director of DCB.

   In determining which applications to put forward, PDs must assess the relative merits of applications, consider the needs of particular investigators in relation to the programmatic goals of the Institute and the funds available. PDs are expected to make sound scientific judgments as to why particular applications should be funded, and must be prepared to present their views effectively to other PDs and senior division staff.

   To strengthen their arguments, PDs may request that applicants submit responses to summary statements, additional data collected during the interval between the SRG meeting and exceptions meeting, and copies of new publications. Applicants may also be asked to provide statements to justify budget requests.

2. Senior staff review the summary statements and exceptions forms and assign members of the program staff as reviewers for each application.

3. The Special Assistant to the Director prepares and distributes copies of the summary statements and forms to reviewers.

On the first day of the exceptions meeting, PDs describe the research proposed in each of the applications put forward for exception funding and present a brief rationale as to why the application should be funded.

After these discussions, a table is generated in which all the applications to be considered for funding are listed. The table includes columns for the priority rankings assigned by the PD, reasons to fund the application, and votes.

On the second day of the exceptions meeting, members of the Senior Advisory Group discuss budget parameters and rank the applications put forward for exception funding. These rankings are communicated back to the branch chiefs and put forward as recommendations to the Director of DCB.

After the meeting:

1. The branch chiefs forward approved exceptions packages to the Deputy Director.

2. The Deputy Director obtains signatures from the Director and from the manager of the Administrative Resource Center (ARC).

3. The ARC manager makes copies of exceptions packages containing the summary statements and exceptions forms for ARC files and returns originals to the Special Assistant to the Director.

4. The Special Assistant to the Director prepares a funding memo and, for applications selected for funding, attaches the original exception forms to the memo, and makes three copies of the package containing the memo and the exception forms.

5. The Special Assistant sends:

   - The original package to GAB.

   - A copy of the entire package to EFDB.

   - A copy of the entire package to the DCB/OD to be retained in the DCB files.

   - A copy of the funding memo to the branch chiefs and the manager of ARC.

   - A copy of the signed exception forms to the appropriate PD.

DCTD Exception Process

DCTB exceptions meetings are held three times each year. To prepare for exceptions meetings, staff members within the branches discuss applications whose priority scores were beyond the payline and decide which applications to put forward for funding.

One week before the meeting:

1. PDs send summary statements of applications to be put forward for exception funding to a program analyst in the DCTD ARC.

2. The program analyst prepares a spreadsheet listing the requests for exception funding by:

   - Funding mechanism.

   - Reason for the exception request.

   - Amount requested.

   - PD’s name and affiliation (i.e., program and branch).

Four days before the meeting, the program analyst sends the spreadsheet, along with copies of the GRITS forms and summary statements to:

- The Director of DCTD.

- The Deputy Director of DCTD.

- All PDs.

At the meeting, budget parameters are discussed, after which PDs present the applications they are recommending for exception funding, along with any modifications to the GRITS form. After each presentation, the application is discussed. Anyone present may ask questions and present points of view. The Director sorts applications into three categories: approved, not approved, or deferred for further consideration.

After the meeting:

1. The Director signs exception forms for approved requests and notifies PDs of final decisions through the program analyst.

2. The program analyst prepares a funding memo specifying the list of approved exceptions request and forwards the memo, along with the signed exception forms, to GAB and EFDB.

In some cases, P01s submitted for exception funding must undergo a second review. Applications for which exception funding would be drawn from the RPG pool must be discussed by the Extramural Division Directors (EDDs) and the EC. P01s for which exception funds would be drawn from division funds do not require further discussion.

DCP Exception Process

To prepare for exceptions meetings, staff members within the branches discuss applications whose priority scores were beyond the payline and decide which applications to put forward for funding.

One week before the meeting of the DCP Coordinating Unit, PDs provide the Director with an exception form and a copy of the summary statement for all applications to be put forward for exception funding.

The Secretary to the Director prepares and distributes copies of the exception package to the members of the Coordinating Unit for review.

DCCPS Exception Process

DCCPS considers applications for exception funding four times each year. PDs submit exception requests to the DAO for approval.

For additional information about exception funding in DCCPS, see "SOPs" and Policies" at http://camp.nci.nih.gov/dccps.

The End-of-Year Funding Process

At the end of the fiscal year, all grants and cooperative agreements can be considered for additional funding. Applications are nominated for end-of-year funding by PDs.

In many cases, requests for end-of-year funding involve grants that do not have out-year obligations (i.e., they are

not funded for the coming fiscal year). Examples of such grants include one-year administrative supplements and funds awarded for the support of scientific conferences.

In some instances, however, the end-of-year process is used to fund applications that received outstanding scores in the peer review process. By funding applications through this process, NCI ensures that high-quality research enterprises will not be disrupted by a gap between the end of one award period and the beginning of another.

The steps for obtaining approval to fund applications through the end-of-year process are as follows.

1. The PD creates a request in GRITS (using the supplement module or the exception module as appropriate) for each application that he or she wants to nominate for funding.

2. The division director either approves or does not approve submitting the application to EDD.

3. The lists of approved applications from all NCI divisions are combined by EFDB and EDD prioritizes them for funding.

4. EFDB coordinates with GAB to assure that awards are issued according to the priority list and the amount of funds available.

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Special Funding Mechanisms

Several special funding mechanisms are available to fund applications submitted by certain investigators or to fund particular kinds of research. These mechanisms include:

- MERIT Awards
- Shannon Awards
- New Investigator Awards (*R01s)

MERIT Awards

MERIT awards (MERIT stands for Method to Extend Research in Time.) are issued to investigators who have demonstrated superior competence and outstanding productivity during their previous research experience.

Nominations for MERIT awards are made when an application is being considered for funding. If the nomination is approved, the recipient will be funded for the period specified in the application and, in addition, will have the opportunity to apply for one to five years of additional funding without submitting a new application for peer review.

Thus, MERIT awards provide distinguished investigators with long-term, stable support to foster their continued creativity.

Selection Criteria for Merit Awards

The following criteria are used to select nominees for MERIT awards.

- The candidate must be the principal investigator (PI) on an unamended competing continuation (Type 2) R01 application that has been supported by NCI for at least seven years.
- The current application must have been assigned a priority score within the 5th percentile and must have been approved by the NCAB for five years of additional support.
- The current application should represent the PI's principal area of research and should be in an area of special scientific importance or promise.
- The candidate PI must be an established scientist, at the leading edge in the proposed research area as indicated by a continuous record of publications in the highest quality journals for that field.

Obtaining Approval to Fund a MERIT Award

Candidates for MERIT awards may be nominated by members of the NCI staff or, in theory, by members of the NCAB.

To obtain approval to issue a MERIT award, the PD must:

1. Identify a potential nominee for a MERIT award and, if required, discusses the nominee with division management.
2. Assemble a nomination package containing the GRITS MERIT form and summary statement. This package is called a special actions package.
3. Submit the package, through the division director, to the Executive Committee for approval.

If the Executive Committee does not approve the nomination, the application is returned to the stream of competing applications and submitted to the NCAB for approval as an R01.

If the Executive Committee approves the nomination, the application is discussed in a pre-Board meeting convened by the Director of DEA. The PD is responsible for making any changes to the application package recommended in this meeting and for ensuring that it is submitted to DEA so that it can be considered by the NCAB.

If the NCAB does not approve the nomination, the application will be funded as an R01.

If the NCAB approves the nomination, the PD must carry out the administrative steps required to process the MERIT award process.

Processing Approved Nominations for MERIT Awards

After the NCAB has approved the nomination of a candidate for a MERIT award:

1. The PD prepares a nomination letter and obtains the signature of the division director.

2. Within two weeks of NCAB approval, the division director signs and distributes the nomination letter.

If the nominee turns down the nomination, the application is funded as an R01.

If the nominee accepts the nomination, he or she must send an acceptance letter signed by an institutional business official to the PD. Upon receiving the acceptance letter, the PD sends a copy of the letter to GAB, and GAB converts the R01 award to an R37 award.

Applying for MERIT Award Extensions

Receiving a MERIT award does not mean that the period of a grant will automatically be extended when the original grant expires. Instead, the applicant must apply for the extension by submitting:

- A progress report.
- A brief description of the research planned for the period of the extension.
- A list of publications and presentations during the period of the MERIT award.

This application is then reviewed within the division and by the Executive Committee and must be approved by the NCAB.

Reviewing Applications for MERIT Award Extensions

MERIT extensions may be approved for one to five years, depending on the degree to which the awardee and the research demonstrate continuing scientific promise, originality, and productivity.

To be approved for the MERIT extension, applicants must meet the following criteria.

- A proposed MERIT extension must be a logical continuation of the current award.

- Applicants for MERIT extensions who propose new, unrelated lines of research or significant changes in their own level of effort or that of key personnel must be advised to submit a regular Type 2 R01 competing application.

- Progress made by the applicant during the current award period must demonstrate continued leadership in the field. The research proposed for the extension period must be at the cutting edge of the discipline, in an area of continued importance to the NCI mission and goals.

The process for reviewing applications for extensions of MERIT awards is as follows.

1. The PD and a Grants Management Specialist (GMS) review the application.

   If the application is not approved, the PD notifies the applicant by letter and recommends that the application be resubmitted as an R01.

   If the application is approved, the PD writes a recommendation for the extension and submits the recommendation, along with the summary statement, to the division director and the Executive Committee.

2. The Executive Committee reviews the application.

   If the application is not approved by the Executive Committee, the PD notifies the applicant by letter and recommends that the application be resubmitted as an R01.

   If the application is approved by the Executive Committee, the application is discussed in a pre-Board meeting convened by the Director of DEA. The PD is responsible for making any changes to the application package recommended in this meeting and for ensuring that it is submitted to DEA so that it can be considered by the NCAB.

3. The NCAB reviews the application.

   If the application is not approved by the NCAB, the PD notifies the applicant by letter and recommends that the application be resubmitted as an R01.

   If the application is approved by the NCAB, the PD sends an approval extension letter to the applicant.

When the application for a MERIT extension has been approved at all three levels, GAB negotiates the specific conditions of the award with the applicant and his or her institution.

Shannon Awards

The Shannon Award is designated as an R55 and is designed to provide a total of $100,000 of support ($80,000 in direct costs, $20,000 in indirect costs) over a single budget period of up to two years. Applications that received priority scores that fell beyond the payline and were not funded through the accelerated executive review or

exception processes may be considered for Shannon Awards.

The Shannon Award provides applicants with a small amount of support to complete studies that might allow them to compete successfully for funds issued through the regular process. Shannon Awards are not intended to sustain or continue a current project. Appropriate uses of a Shannon Award include:

- Testing the feasibility of innovative approaches.
- Developing tests and refining research techniques.
- Performing secondary analyses of available data sets.
- Conducting discrete projects to demonstrate research capabilities.

Eligibility Criteria for Shannon Awards

To be considered for a Shannon Award, an application must be nominated by NCI program staff. After each of the three annual review cycles, Shannon Award nominations are reviewed by NCI division staff. The funds for Shannon Awards are drawn from the division's exceptions pool. An application is eligible for a Shannon Award if:

- The application was submitted under the R01 (either new or competing continuation) or the R03 funding mechanism.
- The application received a priority score that was beyond the payline but above the 50th percentile, or a raw score above 250.
- The applicant does not already have Public Health System (PHS) research support that totals more than $300,000 in direct costs.

Although amended applications may be considered for Shannon Awards, preference is given to unamended (A1) applications. If an amended (A2) application is nominated for a Shannon Award, the nomination package should specify why the amended application should be considered.

Selecting Applications for Shannon Awards

In selecting applications for Shannon Awards, priority should be given to:

- New investigators or investigators who have not yet established significant research programs.
- Senior investigators who are entering new research areas.
- Investigators who are women, members of minority groups, disabled, or members of other disadvantaged groups.

- Applicants who are proposing high-risk projects.

Funding Applications as Shannon Awards

The procedures for funding applications as Shannon Awards are as follows:

1. The PD identifies a candidate for whom a Shannon Award would be appropriate.

   If necessary, the PD may contact the applicant for additional information before proceeding with the award process.

2. The PD prepares an exception in GRITS.

3. The PD prepares and submits a nomination package for the division exceptions meeting.

   During the exceptions meeting, the PD must be prepared to justify the nomination to other members of the Division program staff.

4. The Division Director selects applications for receipt of a Shannon Award.

5. ARC staff in the Office of the Division Director will send approval forms identifying applications that have been selected for Shannon Awards to EFDB and GAB.

6. The PD notifies the applicant that the Shannon Award has been approved.

7. The applicant submits a letter of acceptance co-signed by the appropriate institutional official.

8. GAB negotiates the specific conditions of the award with the applicant and his or her institution.

New Investigator Awards (*R01s)

Each fiscal year, NCI attempts to increase the success rate of new investigators by allocating funds to divisions to support *R01 (pronounced star R01) awards. Divisions may not use funds specifically set aside for *R01s for any purpose other than funding applications submitted by new investigators. They may, however, allocate additional funds for *R01 awards from their discretionary budgets.

If an application submitted by a new investigator is not funded through the regular process, it may be funded as a *R01 application. Applications that are eligible for *R01s must be identified as such when presented to the DAO. (New investigators identify themselves by checking the "New Investigator" box in Item 3 on the PHS 398 application form.) Use of *R01 funds must be approved by the relevant division director.

Applications from new investigators that are not approved for *R01 awards may be submitted for funding through the accelerated executive review or exception process.

Funding Mechanisms with No Payline (R24/U24 and R13)

There are several NCI funding mechanisms do not have a payline. These mechanisms include R24/U24, which are used to fund resource grants, and R13s, which are used to fund conferences.

Funds used to pay grants or cooperative agreements under these mechanisms may be drawn from the non-RPG pool, from funds set aside to issue awards through the exception process, or from divisional discretionary funds.

The procedures for issuing R24/U24 awards are:

1. The PD submits a completed GRITS exception form to the division director for approval.

2. The division director submits applications to the Deputy Director for Extramural Sciences who usually includes them on the EDD agenda.

   If approved by the Deputy Director, the list of approved R24/U24 applications is published on the EFDB website.

The procedures for issuing R13 awards are:

1. The PD submits a completed GRITS form to division director for approval.

2. The division director forwards the approved application to the ARC manager.

3. The ARC manager certifies that discretionary funds to pay the grant are available.

Before the date of the conference, the signed GRITS form must be submitted to GAB for funding and to EFDB for tracking. DHHS policy prohibits issuing awards under the R13 mechanism if the conference has already taken place.

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Co-Funding Applications

Co-funded applications are applications for which NCI provides part of the funds required to issue the award and the remainder of the funds are provided by another governmental or private organization.

Most NCI co-funding agreements involve other NIH Institutes or Centers (IC), but occasionally applications are CO-funded by NCI and another governmental organization. NCI may co-fund applications with private organizations, but has not done so. If desirable opportunities for CO-funding awards arise, PDs should consult senior GAB staff members about how to proceed.

The policies and procedures governing CO-funded awards depend on the amount of the award. For detailed information about CO-funding policies, see http://deaintranet.nci.nih.gov/ncipolicy/cofunding.htm. For information about obtaining approval for CO-funding agreements, see the Levels of Authority document at http://camp.nci.nih.gov/admin/grants/loaindex.htm.

Roles and Responsibilities in CO-Funding Agreements

The IC that initiates the agreement is called the administering or primary funding agent, and the other IC is called the participating or secondary funding agent. The administering IC initiates the agreement and issues the Notice of Grant Award (NGA) to the applicant.

In establishing CO-funding agreements, the ICs agree to fund awards at specific levels. Any changes in the proportion of the award contributed by each of the co-funders or any changes in common accounting numbers (CANs) require the agreement of both parties. Such agreements must be established at least one month before an award is issued.

A grants management contact prepares a Notification of CO-Funding Commitment and is responsible for obligating IC funds and seeking approval from the relevant GMO. The administering IC prepares all worksheets throughout the life of the grant based on the costs stated in the Notification of CO-Funding Commitment. Future-year facilities and administrative costs are to be calculated using the rate in effect when the award was issued.

The administering IC maintains the Notification of CO-Funding Commitment in its files. A copy of the award notice for each year of support, the yearly progress report, and any publications are to be forwarded to the grants management specialist who prepares the Notification of CO-Funding Commitment.

CO-Funding with NCI as the Primary Assignment

An NCI division may be the administering IC in a CO-funding agreement with:

- Another NCI division.
- Another NIH IC.
- An NIH office.
- Other federal agencies.

As noted previously, NCI may establish CO-funding agreements with private organizations but has not, to date, done so.

CO-Funding across NCI Divisions

CO-funding agreements between NCI divisions offer a means of extending the resources of each of the participating divisions. By CO-funding applications, divisions are able to use their resources to support a larger and more diverse set of applications than they would be able to support independently.

CO-funding agreements are used to fund:

- Applications submitted in response to an initiative.

To establish such an agreement, the PD must:

1. Indicate in the funding plan that another division is CO-funding the application.
2. Obtain the approval of the Director of the second division.
3. Ensure that the ARC manager of the second division certifies that funds are available to pay the grant.

- Exception requests.

  In such instances, the PD must specify the amount to be contributed by each division in the GRITS form.

- Initiatives requesting supplemental applications to existing grants or cooperative agreements.

  In such instances, a funding plan is devised by the program or division soliciting the supplemental applications.

CO-Funding with Other NIH Institutes or Centers

CO-funding arrangements with other ICs are often used to fund R13 applications, but applications submitted under other funding mechanisms can also be funded in this way.

To establish a CO-funding agreement with another IC, the PD:

1. Determines the amount to be contributed by the second IC by consulting with the PD in that IC.
2. Identifies a contact person on the grants management staff (GMs) at the second IC

3. Submits the information regarding the CO-funding agreement and the grants management contact to the NCI GMs

NCI GMs requests a GMs worksheet from the second IC. This worksheet must include a CAN number. GMs then issues the award.

To CO-fund applications submitted under other funding mechanisms, an intra-agency agreement may have to be signed. Consult the Levels of Authority document at http://camp.nci.nih.gov/admin/grants/loaindex.html.

CO-Funding Special Initiatives with NIH Offices

Several NIH offices provide resources for supplements to existing grants or CO-funding new or continuing applications. These offices include:

- The Office of Research on Minority Health (ORMH).
- The Office of Special Populations Research (OSPR).
- The Office of Research on Women's Health (ORWH).
- The Office of Dietary Supplements (ODS).
- The Office of Behavioral and Social Sciences Research (OBSSR).

These special initiatives are typically offered once each year.

Office of Research on Minority Health

Dr. John Ruffin, Director

Phone: 301-402-1366

The Office of Research on Minority Health leads the federal effort at NIH in stimulating new research ideas for improving the health status of minority Americans. The Office promotes programs aimed at understanding the participation of underrepresented minorities in all aspects of biomedical and behavioral research.

Contact Information:

Office of Research on Minority Health
6707 Democracy Boulevard
Suite 800
MSC 5465
Bethesda, MD 20892-5466

Phone 301-402-1366
Fax: 301-480-4049

http://www1.od.nih.gov/ORMH/main.html

NCI Office of Special Populations Research

The NCI Office of Special Populations Research shares the goals of the Office of Research on Minority Health and works with NCI program staff to support these goals through the grants issued by NCI.

Contact Person: To Be Named
Executive Plaza South
6120 Executive Boulevard, Room 320
Bethesda, MD 20892
Phone 301-496-8589
Fax: 301-435-9225

http://ospr.nci.nih.gov/

Office of Research on Women's Health

The Office of Research on Women's Health (ORWH) serves as a focal point for women's health research at NIH. ORWH promotes, stimulates, and supports efforts to improve the health of women through biomedical and behavioral research. ORWH works in partnership with the NIH ICs to ensure that women's health research is part of the scientific framework at NIH and throughout the scientific community.

Contact Information:

Lisa Begg, PhD
Director of Research Programs
Building 1, Room 201
9000 Rockville Pike
Bethesda, MD 20892-0162
Phone: 301-402-1770
Fax: 301-402-1798

http://www4.od.nih.gov/orwh/

Office of Dietary Supplements

The Office of Dietary Supplements (ODs) supports research and disseminates research results in the area of dietary supplements. ODs also advises other federal agencies about the results of research on the use of dietary supplements.

Contact Information:

Office of Dietary Supplements
National Institutes of Health
Building 31, Room 1B25
31 Center Drive, MSC 2086
Bethesda, MD 20892-2086
Phone: 301-435-2920
Fax: 301-480-1845
Email:ODs@nih.gov

http://dietary-supplements.info.nih.gov/

Office of Behavioral and Social Sciences Research

Dr. Raynard Kington, Director

The mission of the Office of Behavioral and Social Sciences Research (OBSSR) is to stimulate behavioral and social sciences research throughout NIH and to integrate these areas of research more fully into others of the NIH health research enterprise, thereby improving our understanding, treatment, and prevention of disease.

Office of the Director
National Institutes of Health
Building 1, Room 326
1 Center Drive
Bethesda, MD 20892-0183
Voice: 301-402-1146
Fax: 301-402-1150

http://obssr.od.nih.gov/

CO-Funding with Other Federal Agencies

Establishing CO-funding agreements with grant-makers in other federal agencies usually requires an interagency agreement.

To establish a CO-funding agreement with another federal agency, the PD:

1. Determines the amount to be contributed by the other agency by consulting with the PD in that agency. Identifies a contact person on the grants management staff (GMs) at the other agency. Identifies a contact person on the grants management staff)GMs) at the other agency.

2. Prepares a written justification for the CO-funding arrangement and submits it to the ARC manager for approval.

3. Submits the information regarding the CO-funding agreement, including the signed justification and the grants management contact to the NCI GMs

NCI GMs requests a GMs worksheet from the other agency. This worksheet must include a CAN number. GMs then issues the award.

CO-Funding with NCI as the Secondary Assignment

To establish CO-funding arrangements with NCI as the secondary assignment, the grant that is to be CO-funded must have been approved by the NCAB. Potential CO-funding agreements must be established before the NCAB meeting to assure that the summary statement is included in the Board actions.

To establish a CO-funding arrangement with NCI as the secondary assignment, the PD must:

1. Consult with the PD and the other Institute and with the applicant to ensure that both agree that a CO-funding arrangement is desirable and feasible.

2. Write a justification for the CO-funding arrangement on a GRITS exception form and submit it to the division director.

3. Obtain certification from ARC manager to ensure that funds are available to pay grants from division funds.

4. Submit the signed GRITS form to GAB.

5. Notify the PD in the primary IC that the application has been approved by both program staff and grants administration staff.

GAB staff inform grants management staff at the other Institute that the application has been approved and assign a CAN number. GAB staff may sign inter-Institute or intra-agency agreements.

Transferring Applications from Another Institute or Center

If NCI is interested in funding an application that has a primary assignment at another IC, the application can be transferred to NCI.

If the application does not already have a secondary assignment at NCI, obtaining a secondary assignment for the

application will facilitate this transfer. If NCI has been designated as a secondary assignment for the application, the application will be included in the materials sent to members of the NCAB before their review meeting and can be approved in the en bloc vote.

To add NCI as a secondary assignment, the PD files a 901 form requesting the assignment. The 901 form must be signed by a branch chief and sent to the NCI Referral Office for processing.

If NCI already has a secondary assignment for the application and the priority score is within the NCI payline, RPG funds can be used to pay the grant. To transfer the application, the PD must:

1. Consult with the PD at the other Institute to ensure that a transfer is both feasible and desirable.

2. Obtain permission for the transfer from his or her branch chief or division director.

   NCI RPG paylines may be more favorable to applicants than the paylines of other ICs. Thus, it is essential to control the number of applications reassigned to NCI. Program staff must ensure that the application is compatible with NCI's funding plan and that the funds are available to pay the grant before a transfer can be accepted.

   If the re-assignment to NCI is completed prior to NCAB concurrence review, the grant will appear on the relevant paylist. When the reassignment to NCI is completed after the NCAB meeting, the PD must use the division exception process to request division exception process to request division funding of the grant. The 901 form (see next step) should not be submitted until after the division director has made the commitment to pay such an application within the NCI payline for the relevant mechanism.

3. File a 901 form requesting the transfer.

   The 901 form must be signed by the branch chief and sent to the NCI Referral Office for processing.

If NCI already has a secondary assignment for the application and the priority score is beyond the NCI payline, division-controlled funds can be used to pay the grant. To transfer the application, the PD must:

1. Consult with the PD at the other Institute to ensure that a transfer is both feasible and desirable.

2. Present the application for funding in the division's exception process.

   For more information about the exception process, see Funding Applications through the Exception Process.

If the application is approved for funding, the PD must file a 901 form requesting a transfer. The 901 form must be signed by the branch chief and sent to the NCI Referral Office for processing.

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Review of Applications Prior to Award

Review of Applications Prior to Award

This section specifies procedures for reviewing applications before awards are issued. The tasks associated with this review can be organized into four broad categories. These categories are:

- Identifying applications that are eligible for expedited review and early NCAB concurrence.

- Identifying applications that must be called to the attention of the NCAB at its scheduled meetings.
- Ensuring that the application provides the information about the conduct of the research and the oversight of the grantee organization that is legally required.
- Completing the administrative tasks required to issue the award.

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Identifying Applications that Are Eligible for Expedited Review

In certain cases, applications may be approved electronically. Such applications include applications that are eligible for expedited NCAB concurrence and early approval, as well as other applications for which NCAB approval is not required.

This process may be used to fund:

- Unsolicited Type 1 and Type 2 R01s that have priority scores within the payline.
- Exploratory/Developmental Grants (R21s).
- Small Grants, i.e., grants for less than $50,000 in direct costs issued under the R03 mechanism.

The expedited process **may not be used** to fund:

- Foreign applications or domestic applications with a foreign component.
- Applications for which the SRG identified concerns about the protection of human subjects, the welfare of laboratory animals, or biohazards.

Applications submitted under the R01 mechanism that are eligible for funding through the expedited process are automatically identified by NCI, and PDs are notified by email about the applications in their program areas that are eligible for funding through this process.

Upon receipt of this email, PDs must indicate, for each application on the list, whether payment of the grant is approved. To carry out this activity, the PD must use the interactive system available at http://deaxtra.nci.nih.gov/ncab/new-intranet/ncab/new-logon.htm.

To indicate whether payment of the grant is approved, log on using the userid and password assigned for use in IMPAC II. Under "Voting Action," select "OK to Pay" or specify a reason not to pay. Choosing not to pay is warranted when there is a concern (e.g., about human subjects issues) that must be resolved before the application can be approved for payment or when program staff have decided to skip that application in the paylist.

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Identifying Applications that Must Be Reported to the NCAB

Most of the applications presented for review at NCAB meetings are approved en bloc. That is, based on the judgments of the peer reviewers, the NCAB approves the applications for funding without reviewing each application individually.

Some applications, however, **must** be called to the attention of the Board. These applications include:

- Foreign applications.
- Applications for which the SRG noted concerns about the welfare of human subjects, the welfare of laboratory animals, or biohazards.

Foreign Applications

The use of US funds for research conducted at foreign institutions must be called to the attention of the NCAB and then approved by the Department of State.

An application is considered foreign if:

- The organization to which a grant would be awarded is foreign, i.e., it is not under the control of the US government, a US institution, or a US business.
- The application involves a foreign collaborator or subcontractor who would receive more than $10,000 in funding.
- Data involving human subjects, including tissue specimens, would be collected at a foreign site.
- Data involving research animals would be collected at a foreign site.

Applications that involve a foreign component, but are submitted by domestic institutions, need not be reported to the NCAB.

Before each meeting of the NCAB, the Chief of the DEA Special Review and Resources Branch (SRRB) distributes a memo that contains instructions and a timetable for reporting foreign grants to the NCAB. This memo is titled "Preparation of Staff Recommendations and Informational Items for the Special Actions Subcommittee Meeting."

For information about special requirements for foreign applications, see Processing Foreign Applications.

Applications that Involve Concerns about Biohazards

If the summary statement indicates that the SRG has noted concerns about biohazards, the application must be

called to the attention of the NCAB.

To fulfill this requirement, submit two copies of the summary statement and a synopsis of the concern taken verbatim from the summary statement to DEA.

To obtain information about the timeline and format for these materials, see "Preparation of Staff Recommendations and Informational Items for the Special Actions Subcommittee Meeting." This document is distributed by SRRB before each NCAB meeting.

For more information about handling applications that involve biohazards, see Resolving Concerns about Biohazards.

Applications that Involve Concerns about Human Subjects or Laboratory Animals

Applications for which the SRG identified concerns about the welfare of human subjects or laboratory animals must be called to the attention of the NCAB.

These applications can be identified by examining the codes and Administrative Notes in the summary statement. When such problems are identified, the PD must attempt to resolve the problem through discussion and the exchange of information with the applicant and, if necessary, the applicant's institution.

Unless there is an exceptional situation which must be brought to the attention of the NCAB, it is not necessary to prepare material relating to applications with adverse human subjects or animal welfare codes for the NCAB.

These applications will be identified in a special list that will automatically be included in the NCAB books.

For more information about handling applications that involve these concerns, see:

Resolving Concerns about the Safety and Privacy of Human Subjects
Resolving Concerns about the Use and Care of Animals

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Reviewing Applications that Involve Biohazards

If the SRG has expressed concerns about the production or use of materials that constitute biohazards, these concerns must be addressed before an award can be issued.

Identifying Applications that Involve Biohazards

If the SRG expressed concerns about biohazards, the summary statement will contain a Special Note describing

their concerns.

If there is no note on this topic in the summary statement, no further administrative action with regard to this topic is required.

Resolving Concerns about Biohazards

To resolve concerns about biohazards identified by the SRG, the PD must:

1. Notify-by fax or US Mail-the applicant and his or her institution of the concerns identified by the SRG and request a written response.

2. Write a concurrence memo indicating that the concern has been satisfactorily resolved. (If the applicant's response is not satisfactory, the PD may recommend that the applicant further consider the concerns of the SRG and submit a new response.)

3. Send the memo, the applicant's response, and a copy of the summary statement to the NIH Division of Safety for approval.

4. Send the signed memo and the applicant's response to the GMS who will be handling the award process for that application.

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Reviewing Applications that Involve Human Subjects

Research regarding any manifestation of living individuals-from intracellular mechanisms to employment records-is governed by US law concerning the involvement of human subjects in federally-funded investigations.

The Office of Human Research Protections (OHRP) in the Department of Health and Human Services (DHHS) specifies policies for research involving human subjects and oversees compliance with those policies. Information about these policies is available at http://ohrp.osophs.dhhs.gov/.

For information about DHHS policies as they apply to grant-making at NIH, see http://www3.od.nih.gov/oma/manualchapters/grants/4107/main.html.

For information about the operational details of human subjects policies at NCI, see http://deainfo.nci.nih.gov/grantspolicies/index.htm.

Identifying Applications that Involve Human Subjects

Applications must be evaluated in terms of their compliance with human subjects requirements if the research plan indicates that:

- Data will be collected through interactions with living individuals.
- Data about the effects of interventions in the lives of living individuals will be collected.
- Data about private identifiable aspects of the lives of individuals (e.g., medical history) will be collected.

If the research proposed in an application involves human subjects, the following indicators will be present:

- Item 4 on the face page of the application should be checked.
- Plans for the participation and protection of human subjects will appear in the Human Subjects section of the application.

The Instructions for Form 398, pp. 17-27, specify how the Human Subjects Research Section of the application should be prepared. Those instructions may also provide a useful reference for PDs. They are available at ftp://grants.nih.gov/forms/phs398.pdf.

Determining Whether the Application is Exempt

Certain research involving human subjects is **exempt** from DHHS regulations governing the use of human subjects. Create link to section called "Assessing the Adequacy of Protections for Human Subjects" in Chapter 1.

Applicants may indicate-on the face page of the application-that the proposed research should be exempt.

If reviewers agree with the applicant's claim that the proposed research should be categorized as exempt, no further administrative action with regard to this issue is required.

If reviewers disagree with the applicant's claim that the proposed research should be categorized as exempt, that disagreement will be noted in the summary statement under the Human Subjects heading.

This note will characterize the concerns of the SRG and, in doing so, point to problems that the PD must attempt to resolve.

Resolving Concerns about the Safety and Privacy of Human Subjects

In reviewing applications, SRGs assess the applicant's plan for protecting human subjects from research risks and for informing them about exposure to any risks.

If the Human Subjects code is not 44 or 49, the SRG found the applicant's plans for protecting human subjects to be satisfactory. No further administrative action on this topic is required.

If the Human Subjects code is 49, the SRG identified human subjects concerns and the SRA noted that the application did not specify required assurance numbers.

For applications that received Human Subjects codes of 44 or 49, the PD must:

1. Inform the applicant and his or her institution of the concerns identified by the SRG in a letter sent by US Mail.

2. Summarize the applicant's response to the concerns in a concurrence memo.

3. Send the concurrence memo to the NIH Office of Extramural Research (OER).

4. Attach the concurrence memo to the application so that the memo will be available for NCAB review.

Even if the priority score assigned to the application suggests that the application is not likely to be funded, the PD must communicate the human subjects concerns noted by the SRG to the applicant as the concerns must be resolved before the application can be resubmitted.

Resolving Concerns about the Inclusion of Women, Members of Minority Groups and Children

For each application involving human subjects, the summary statement indicates whether the SRG viewed the applicant's plans for including women, members of minority groups, and children in the research as consistent with NIH policy. This information is provided in acceptability codes at the top of the summary statement.

Each application should have three codes. These codes refer to:

- The gender composition of the participant group.
- The racial or ethnic composition of the participant group.
- The age composition of the participant group.

For a detailed explanation of this coding system, see Coding Single Component Applications. Create link to section with this heading in Chapter 1.

The codes regarding the composition of the participant group and the judgments of the SRG about that composition contain three characters. The third character in the codes for gender composition, racial composition and age composition will be either **A** or **U**.

If the inclusion code for all three variables is A, the SRG found the applicant's plans for composing the group of research participants acceptable. No further administrative action on this topic is required.

If the inclusion code for any variable is U, the SRG found the applicant's plans for composing the group of research participants unacceptable for that variable.

For applications that were coded as unacceptable, the PD must:

1. Request that the applicant justify, in writing, the appropriateness of the composition of the participant group.

2. Write a concurrence memo to the Director of DEA indicating that the justification is satisfactory. (If the information provided by the applicant does not respond satisfactorily to the concerns of the SRG, the PD may recommend that the applicant revise and resubmit the justification.)

3. Send the memo, the applicant's response to the concerns of the SRG, and a copy of the summary statement to the Director of DEA for approval.

4. Send the signed memo and the applicant's response to the GMS who will be handling the award process for that application.

Checking Assurances

Before grants for research involving human subjects can be issued, applicants are required to submit:

- An Assurance of Compliance number.

  Institutions must have an approved Institutional Assurance of Protection for Human Subjects on file with the DHHS OHRP. To determine whether the institution has an Assurance on file, see http://ohrp.osophs.dhhs.gov/irbasur.htm.

  If the grantee institution or any collaborating institution (including foreign institutions) does not have an Institutional Assurance, direct the applicant to the DHHS OHRP website to obtain instructions for registering IRBs and filing Federalwide Assurances for Protection for Human Subjects.

- Documentation of review by an IRB.

  Any application in which the research plan involves the use of human subjects must be reviewed by the applicant's IRB.

- Certification that all key personnel have completed training in the protection of human subjects.

Assessing the Adequacy of Data and Safety Monitoring Plans

All applications that involve clinical trials must include a Data and Safety Monitoring Plan (DSMP) in the Research Design and Methods section.

For more information about the topics to be included in the discussion of data and safety monitoring, see *Procedures to Minimize Risk* on this website or http://cancertrials.nci.nih.gov/researchers/dsm/index.html. Create link to this phrase in Chapter 1. Find phrase in numbered list under Procedures for the Participation and Protection of Human Subjects.

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Reviewing Applications that Involve Vertebrate Animals

If vertebrate animals are included in the research, the applicant must describe the type and number of animals to be used, provide a rationale for choices regarding the use of animals, and specify procedures to insure that animals are well cared for and do not experience unwarranted pain or distress.

Responsibility for ensuring that an applicant has met these requirements rests with the SRG. If an application does not meet these requirements, it may be returned without peer review.

Identifying Applications that Involve Vertebrate Animals

If the research proposed in an application involves vertebrate animals, the following indicators will be present:

- Item 5 on the face page of the application should be checked.
- Plans for the use and care of laboratory animals will appear under the appropriate heading in the application.

Resolving Concerns about the Use and Care of Animals

In reviewing applications, SRGs assess the applicant's plan for ensuring the welfare of laboratory animals.

If the Animal Welfare code is 30 or below, the SRG found the applicant's plans for the use and care of laboratory animals to be satisfactory. No further administrative action on this topic is required.

If the Animal Welfare code is 32, 44, 47, or 48, the SRG expressed comments or concerns about the welfare of laboratory animals.

For applications that received Animal Welfare codes of 32, 44, 47, or 48, the PD must:

1. Inform the applicant that a revised protocol for the use and care of animals in the proposed research must be submitted.

2. Write a concurrence memo indicating that the revised protocol is satisfactory. (If the revised protocol is not satisfactory, the PD may recommend that the applicant revise and resubmit the protocol.)

3. Send the memo, the revised protocol, and the summary statement to the Director of DEA for approval.

4. Send the signed memo and the applicant's response to the GMS who will be handling the award process for that application.

Even if the priority score assigned to the application suggests that the application is not likely to be funded, the PD must communicate the animal welfare concerns noted by the SRG to the applicant as the concerns must be resolved before the application can be resubmitted.

Checking Assurances

To determine whether the applicant and the grantee institution have provided the information required to assure the humane use and care of laboratory animals:

- Check the date of assurances from the applicant's Institutional Animal Care and Use Committee (IACUC).

  The IACUC approval date must be no more than three years old. Both the date of the assurance and the animal welfare assurance numbers appear on the face page of the application

- Check the animal welfare code in the summary statement.

  If the code is 32, assurances regarding research to be conducted at a foreign institution or research to be conducted in the future may be required. If the code is 45 or above, the required assurances are missing.

If the summary statement indicates that the animal welfare assurance is outdated or that the applicant did not specify the date of the IACUC, the PD must notify-by fax or US Mail-the applicant and his or her institution about the missing information and request that it be submitted.

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Reviewing Applications that Involve Human Embryonic Stem Cells

NIH policies for the use of human embryonic stem cells are currently being developed. The stem cell lines currently

approved for research purposes are listed at the following website.

http://www.nih.gov/news/stemcell/082701list.htm

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Processing Foreign Applications

Foreign applications are subject to the same review standards as other applications, but extra steps are required to obtain approval to fund them. Foreign applications must be formally presented for NCAB approval and must also be approved by the Department of State.

For instructions about submitting foreign applications for NCAB approval, see the memo titled "Preparation of Staff Recommendations and Informational Items for the Special Actions Subcommittee Meeting," which is distributed by the Chief of SRRB before each NCAB meeting.

To obtain State Department approval, the PD must submit a copy of Form 1820, the application, and the summary statement to the Fogarty International Center. After completing its review, the Fogarty Center will return the form to the PD. This form should be sent to GAB along with a copy of the green sheet.

For a comprehensive presentation of the information required to process foreign applications, including an online version of Form 1820, see http://odoerdb2.od.nih.gov/gmac/topics/foreign_main.html.

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Completing Administrative Requirements

After applications have been reviewed and approved for funding, PDs must complete the administrative tasks required to issue awards. After these tasks are completed, PDs submit the applications to the Grants Administration Branch (GAB). Subsequently, Grants Management Officers (GMOs) negotiate the specific conditions of the award and pay the grants (i.e., encumber the funds).

For some applications, PDs will need to carry out specific tasks that have to do with the character of the project or the circumstances of the investigator. For most applications, however, PDs will need only to complete the Grant Documentation Control Form for Competing Applications Form, i.e., the "green sheet." **A green sheet must be completed for every application.**

Converting Grants to Cooperative Agreements

If the research plan presented in an unsolicited application indicates that NCI staff will play a substantial role in the

proposed work, the award must be converted from a grant to a cooperative agreement. In such cases, grants to be funded under the R01 mechanism are converted to U01s, and grants to be funded under the P01 mechanism are converted to U19s.

"Substantial involvement" means that NCI staff will make both intellectual and practical contributions to the research. It is the responsibility of the PD to identify grants in this category.

- PDs may use the following examples as indications that a grant should be converted to a cooperative agreement.
- An NCI staff member directs a project within a program project (P01) grant.
- An NCI staff member is responsible for achieving one of the specific aims of an R01 grant.
- NCI staff develop a major database for an extramural collaborator.
- NCI staff participate in the execution of clinical, prevention or epidemiological studies through a multi-institutional collaborative arrangement with extramural researchers.

To convert the award, the PD must:

1. Prepare a memo which describes the substantial collaboration and specifies the terms and conditions of the award for both awardees and NCI staff
2. Send the memo to Office of Review, Referral and Program Coordination in DEA to be signed.

DEA works closely with GAB on each case, creating a memo about the award conversion which is then forwarded to the NIH Office of Programs for approval. Most conversions from unsolicited applications require specialized cooperative agreement terms. These terms must be cleared through GAB, NCI and NIH.

DEA specifies Standard Cooperative Agreement Terms, which are included in the award letter.

Specifying Milestones for R21/R33 Phased Innovation Awards

The summary statement for an R21/R33 application will include a Critique of Milestones section. The PD must review this section and determine whether the SRG has requested additions or changes.

If so, the PD must contact the PI and request that the required information be provided in writing. An approved version of the milestones will appear in the Notice of Grant Award.

For more information about R21/R33 applications, see Soliciting Applications for Technology Research.

Issuing Certificates of Confidentiality

A certificate of confidentiality (COC) protects an investigator from being required to release research records that could be used to identify research participants in a legal proceeding.

PDs may identify applications that would be eligible for coverage by a COC and notify the investigator about this possibility. For information about the kinds of research that might be covered, see http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

To apply for a COC, the investigator must submit:

- The application form, which is identified as Attachment C, and is available under Extramural Investigator at the website noted below.
- Documentation of review by the IRB.
- Copies of the informed consent forms to be used in the study.

For more detailed instructions about applying for COCs, see http://cancertrials.nci.nih.gov/researchers/safeguards/certificates/page02.html.

Applications are reviewed by a subcommittee of the NCI IRBs, and applications recommended for approval must be signed by the NCI deputy director.

The Certificate of Approval does not protect against a request for data under the Freedom on Information Act or the A-110 Amendment and does not exempt the entire dataset.

Checking Scientific and Budgetary Overlap

PDs must review applications to determine whether issuing an award under the terms indicated in the application would lead to scientific, technical, or budgetary overlap.

- If the purpose of the proposed research is highly similar (e.g., one or more specific aims of the research are identical or nearly so) to a currently funded grant, scientific overlap may exist.
- If the resources to be used in the execution of the research (e.g., reagents, animal colonies) are the same as those used to perform the work specified in a currently funded grant, technical overlap may exist.
- If funding the application would result in a commitment of more than 100% effort on the part of any key personnel, adjustments in effort and associated salary must be made.

An individual may not receive an award that would result in a commitment of more than 100% of his or her time. Nor can the same research enterprise be funded simultaneously by two agencies or by two grants from the same agency.

To assess the extent of overlap, the PD must:

- Review any Administrative Notes in the summary statement that address overlap issues.
- Compute the total percent effort for the applicant and all key personnel.
- Evaluate comments about other support provided in the application.
- Obtain updated information about other support from the investigator.

If the PD identifies scientific or technical overlap or overlap in the commitments of key personnel, a reduction in the project budget may be warranted.

Evaluating Overlap in Traditional Applications

Applicants who submit applications with budgets that exceed $250,000 per year in direct costs are required to provide information about other support at the time of submission. As basic documentation has already been provided, PDs may call investigators to request updated information about other support and accept the information they obtain in those conversations. No additional formal documentation is required.

Evaluating Overlap in Modular Applications

As the modular application does not require that applicants include information about other support, formal documentation about other support must be obtained before an award can be issued, i.e. "just in time." NIH automatically sends a letter requesting this information from any investigator who has a pending R01 with a percentile score of 30% or better.

If an application is being considered for approval through the exception process, the PD must request information about other support from the investigator. The PD may recommend that the investigator use the format specified in PHS Form 398 to report on other support.

In response to this letter the investigator must provide information directly to regarding all current funding, as well as current funding for each of the key project personnel. The investigator's report should include:

- The total budget.
- The percent effort of key personnel.
- The specific aims of other awards
- A description of the technical and scientific overlap of the current award and awards previously issued.

For other funding mechanisms, such as R21, P01s, U01s, and Center grants, the PD must request all the information about other support from the investigator. The other support statement must be signed by an institutional business official. If there is no other support, the official may notify GAB of this fact by email.

If an R01 application with a percentile score greater than 30% is to be funded through the exception process, the

PD must request information about overlap from the investigator as soon as funding is authorized.

Completing Green Sheets

In completing the green sheet, the PD is issuing final approval to fund the application. This approval authorizes GAB staff to negotiate the specific terms and conditions of the award with the grantee and the grantee institution. A green sheet must be completed for every grant.

Follow the steps below to complete the green sheet.

1. Funding Level

   a. Enter percent of corrected recommended funding level or enter the dollar amount of the decrease in direct costs from the corrected recommended level. Delete the items/dollars specified under Remarks and indicate whether to use a term to prohibit the rebudgeting of awarded funds for those items.

   b. If the period of the recommended competitive segment is to be reduced, enter the number of years for the funded period. Provide justification.

   c. Special FundingIndicate the recommended funding level according to NCI funding plans or in line with special considerations.

   - Exceptions, Shannon Awards, Supplementary Awards, *R01 awards. Attach GRITS form to the green sheet before submitting to GAB.

   - MERIT Awards approved by the NCAB.

   - MERIT Award extensions approved by the NCAB.Include a copy of the extension nomination document edited to include the NCAB recommendation.

2. Human Subjects

   Check Yes or No to indicate whether the research proposed in the application involves human subjects.

   a. If applicable, enter the exemption number indicated on the summary statement.

b. If applicable, check Yes or No to indicate whether the awardee has approved assurance.

If applicable, check Yes or No to indicate whether assurances have been filed for the performance site(s).

If assurances are needed, indicate whether the necessary documents have been sent to the Office of Human Research Protections (OHRP) and specify the date on which they were sent.

c. Indicate that the gender and ethnic composition of the participant group is coded as acceptable (A) on the summary statement. If the application was originally coded as unacceptable (U), ensure that the problem identified by the SRG has been resolved before proceeding.

d. Determine whether the type of research described in the application is exempt from tracking patient recruitment and the recruitment of women and members of minority groups.

If the research is exempt, enter the appropriate Exception Code from the list on the back of the green sheet.

If the research is not exempt, review the plans presented in the application for the recruitment of patients and the recruitment of women.

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Administrative Supplements

Administrative supplements are funds awarded to investigators based on the professional judgments of NCI staff. Applications for administrative supplements are not submitted for peer review. Instead, PDs review requests for supplements and determine whether the request is within the aims of the original project, as specified in the peer-reviewed and funded application.

Administrative supplements are used to provide funds to:

- Pay expenses that were not foreseen when a new, noncompeting continuation, or competing continuation application was submitted
- Expand an already-funded research enterprise within the scope of the approved application.
- Support opportunities for research training for members of minority groups, people with disabilities, and individuals who are reentering research careers.
- Support research enterprises that are co-funded with NIH offices.
- Support a research program between the end of one grant and the beginning of another.
- Phase out an existing research program in an orderly way.

NIH policies on administrative supplements are available at http://grants.nih.gov/grants/policy/nihgps/part_ii_1.htm. At this Web site, the following heading, "Part II: Terms and Conditions of NIH Grant Awards-Part 1 of 7 Part II: Terms and Conditions of NIH Grant Awards-Part 1 of 7" will appear. The relevant material is in Parts 5, 6, and 7.

Requests for General Administrative Supplements

General administrative supplements are used to provide funds needed to:

- Pay for items already specified in the budget of a funded project whose cost has increased.
- Pay for items essential to the approved project but not anticipated at the time of the application.
- Restore components of an application (i.e., specific aims, subprojects) cut during the review and funding process.

- Provide support for training in cancer-related research for members of minority groups, people with disabilities, and individuals reentering a research career after a substantial interruption.

For more information about administrative supplements, see http://odoerdb2.od.nih.gov/gmac/sources/sources.html.

To move directly to the discussion of a particular kind of general administrative supplement, click on one of the links below.

Investigator-Initiated Requests for Supplements

Applicants who wish to seek administrative supplements must submit a request directly to the PD who is administering the current grant.

Such requests may be submitted at any time. There is no specific format for such requests. A standard business letter is acceptable. Requests for supplements for different projects within a P01 grant or a SPORE grant require separate applications.

The applicant must justify the request for additional funds by explaining why the funded project cannot be accomplished within the budget for that application. A budget specifying how the supplement would be spent should be attached to the request.

To process investigator-initiated requests for administrative supplements, the PD must:

1. Verify eligibility by making sure the applicant holds an active parent grant.

   If the applicant is ineligible for an administrative supplement, the PD must return the request for supplemental funds to the applicant.

2. Review the application to determine whether it bears the appropriate institutional countersignature and is otherwise correct and complete.

   If required information is missing or appears to be incorrect, the PD must contact the applicant, explain the problems, and invite the applicant to submit a revised application.

3. Complete a GRITS form for the application.

4. Prepare a memo summarizing the applicant's request and the rationale for funding the application.

5. Submit the packet containing the GRITS form, the application, and the memo for approval of the funding request according to the procedures established for each division.

   In DCB, route the packet through the branch chief, the division director and the Extramural Division Directors (EDD), according to the Levels of Authority document. The Levels of Authority document is available at http://camp.nci.nih.gov/admin/grants/loaindex.htm.

   In DCTD, route the packet through the branch chief, the division director, and the EDD, according to the Levels of Authority document.

   In DCP, route the packet through the research group chief, the coordinating unit, and the EDD, according to the Levels of Authority document.

   In DCCPS, route the packet through the branch chief, the associate director, and the senior advisory group (SAG). After approval by the SAG, the packet will be sent to the OD of DCCPS for approval and then routed to the EDD.

6. After the application is approved, send the packet to:
   - The Section Chief, GAB.
   - The Branch Chief, EFDB.
   - The Division Administrative Resource Center (ARC).

7. Notify the applicant about the outcome of the approval process.

For more information about investigator-initiated requests for administrative supplements, see http://camp.nci.nih.gov/dccps.exceptions.htm.

Requests for Supplements Submitted in Response to NCI Initiatives

Special initiatives requesting applications for supplementary funds are published in the NIH Guide under Notices. For examples of such notices, see http://deainfo.nci.nih.gov/extra/notices/index.htm.

Applicants who wish to seek administrative supplements must submit a request directly to the PD who is administering the current grant by the deadline specified in the published notice.

There is no specific format for such requests. A standard business letter is acceptable. Requests for supplements for different projects within a P01 grant or a SPORE grant require separate applications.

The applicant must justify the request for additional funds by explaining why the funded project cannot be accomplished within the budget for that application. A budget specifying how the supplement would be spent should be attached to the request.

Processing Requests for Supplements Submitted in Response to NCI Initiatives

The process for obtaining approval to fund requests for supplements submitted in response to initiatives is established by the program staff managing the initiative.

In general, however, the PD must:

1. Verify eligibility by making sure the applicant holds an active parent grant, is a partner in a current cooperative agreement, or is a party to a current contract.

   If the applicant is ineligible for an administrative supplement, the PD must return the request for supplemental funds to the applicant.

2. Review the application to determine whether it bears the appropriate institutional countersignature and is otherwise correct and complete.

   If required information is missing or appears to be incorrect, the PD must contact the applicant, explain the problems, and invite the applicant to submit a revised application.

3. Notify the staff managing the initiative when an application is received so that they can update their records of responses to the initiative and begin to develop plans for allocating the available funds.

4. Complete a GRITS form for the application.

After all applications have been received, processed, and reviewed, the program staff who issued the initiative will develop a funding plan and submit it to the EDD for approval.

After funding decisions have been made, the PD must:

1. Send the approved application and the GRITS form to:

   - The Section Chief, GAB

   - The Branch Chief, EFDB

   - The Division Administrative Resource Center (ARC).

2. Notify the applicant about the outcome of the approval process.

Requests for Individual Supplements: Minority, Disability and Reentry

Individual supplements are intended to support the career development of members of minority groups, individuals

with disabilities, and individuals reentering a research career after a significant absence or gap in employment as a researcher.

Applications for individual supplements must be initiated by the principal investigator on a current grant. Further information about the goals of these programs, eligibility requirements, and instructions for applications are available at the Web sites indicated below.

- Research Supplements for Underrepresented Minorities

  Includes supplements for high school students, undergraduate students, graduate research assistants, postdoctoral training, and minority investigators. For more information, see http://grants.nih.gov/grants/guide/1997/97.11.07/n1.html.

- Research Supplements for Individuals with Disabilities

  Provides funds to recruit and support scientists and students with disabilities. This program will also provide support for NIH investigators who become disabled, such as assistants or special equipment. For more information, see http://grants.nih.gov/grants/guide/1997/97.11.07/n2.html.

- Supplements to Promote Reentry into Biomedical and Behavioral Research Careers

  Supports full-time or part-time work for individuals with high potential to reenter an active research career after taking time off to care for children or parents or to attend to other family responsibilities. For more information, see http://grants.nih.gov/grants/guide/pa-files/PA-97-088.html.

Processing Requests for Individual Supplements

The Comprehensive Minority Biomedical Branch (CMBB) oversees the processing of all applications for individual supplements (minority, disability, and reentry). The PD responsible for administering the parent grant works with CMBB to process the application.

The steps in this process are:

1. CMBB sends a copy of the application, a copy of the NCI Referral Office assignment sheet, and an evaluation form to the PD who is administering the parent grant.

2. The PD signs the assignment sheet and returns it to the NCI Referral Office.

3. CMBB reviews the application for eligibility.

   If the applicant is found to be ineligible, CMMB notifies the applicant by letter and sends one copy of the letter to the PD administering the parent grant and one copy to GAB.

   If the applicant is found to be eligible, CMMB notifies the applicant by letter, enclosing a copy of a Personal Data Sheet requesting information from the minority investigator.

4. The PD returns the evaluation form to Bobby Rosenfeld in CMMB within two weeks of receiving it.

   Hard copies can be sent to EPN 620. Email versions can be sent to rr63v@nih.gov.

5. CMBB takes the application through the approval process.

6. After the approval process is complete, GAB sends a Notice of Grant Award to the institutional business office, CMBB, and the PD.

7. CMBB notifies the applicant and the minority investigator (or student) that the application for the supplement has been approved.

8. GAB sends the PD who is administering the parent grant a control sheet (a green sheet with MIN stamped on it) to be completed.

9. The PD signs the green sheet, activating the supplement.

Reviewing Progress Reports

Principal investigators are required to send progress reports concerning the individual named in the application for an individual supplement to GAB. GAB sends copies of the progress report to CMBB and the PD, along with a IIA Non-Competing Application green sheet, for approval.

If no progress report is received, or if the progress report is unsatisfactory, CMBB contacts the principal investigator to request a report or a revised version of an already-submitted report. When the report is received, CMBB sends copies to GAB and the PD.

Co-Funding Supplements

NIH offices such as the Office of Research on Minority Health, the Office of Women's Health, and the Office of Nutrition and Dietary Supplements participate in Research Enhancement Award Programs (REAP), which may include funds for administrative supplements. Post-award supplements through these offices or for other for Co-funded applications are allowed and are subject to the NCI Levels of Authority rules.

Obtaining Approval for a Co-Funding Supplement

The process for obtaining approval to issue supplements for Co-funded applications is similar to the process used to approve and award exceptions. The steps in this process are:

1. The PD nominates a grant for co-funding, prepares an exception form, and sends copies of the document to the relevant ARC.

2. The ARC determines whether funds are available.

3. The division director reviews the exception form and determines whether to fund the application.

4. If approved by the division director, the Deputy Director of Extramural Sciences (DDES) reviews the application.

5. If approved by the DDES, the ARC sends copies of the approved form to GAB and EFDB.

For more information about Co-funding, see Co-Funding Applications.

Phase-Out Support

Phase-out support may be provided for grants and cooperative agreements that will not be renewed. Phase-out awards are intended to provide a minimal level of support to close out research activities funded under current grants.

To obtain phase-out support, the grantee must submit a request for a non-competing extension of the project period. Applications may be submitted at any time. No special format is required. The application must present a justification for an administrative supplement to complete the project and specify a new end date.

A budget for the continuation period must be included in the application packet. The application must be signed by the applicant and an authorized institutional business official.

For more information about phase-out awards, see http://www3.od.nih.gov/oma/manualchapters/grants/4802.htm.

Interim Support or Bridge Funding

Interim support is intended to provide minimal funding to maintain continuity in research enterprises or to obtain additional data that would allow the investigator to re-compete for renewal of a current grant.

Interim support may be appropriate for investigators who have submitted a competitive renewal and narrowly missed the payline, but who have a strong chance of being funded based on an amended application.

For information about obtaining approval of requests for interim support, see the Levels of Authority document at http://camp/nci.nih.gov/admin/grants/loaindex.htm.

In addition to these general guidelines, divisions may have their own policies or procedures.

DCB Interim Support Procedures

The criteria for obtaining interim support within DCB are:

- The applicant must be a candidate for a Type 2 R01 award.
- The applicant must have received a priority score within approximately 15 points of the payline.
- The summary statement must indicate that problems identified by the SRG can be successfully addressed in an amended application.
- The original application (i.e., not an amended application) must be used as the basis for determining whether an applicant should receive interim support.

To apply for interim support, the investigator must:

1. Submit a minimal budget specifying salaries for essential personnel and the support of specific research resources (e.g., a mouse colony).
2. Submit a justification for the extension, signed by an institutional business official.

To process the application, the PD must:

1. Submit the request for the extension on a GRITS form, indicating that the request is for a supplement.
2. Follow the steps specified in the Levels of Authority document to obtain approval to fund the application.

In general, DCTD funds applications for interim support for periods up to four months. The criteria for obtaining interim support within DCTD are:

- The applicant must be a candidate for a Type 2 R01 award.
- The applicant must have received a priority score within approximately 15 points of the payline.
- The summary statement must indicate that problems identified by the SRG can be successfully addressed in an amended application.
- The original application (i.e., not an amended application) must be used as the basis for determining whether an applicant should receive interim support.

To apply for interim support, the investigator must:

1. Submit a budget specifying salaries for essential personnel and the support of specific research resources (e.g., a mouse colony).

2. Submit a justification for the extension, signed by an institutional business official.

To process the application, the PD must

1. Submit the request for the extension on a GRITS form, indicating that the request is for a supplement.

2. Follow the steps specified in the Levels of Authority document to obtain approval to fund the application.

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Competing Supplements

Competing supplements are intended to provide support to expand the scope of a research project or program. To be eligible for a competitive supplement, the investigator must have at least two years of support remaining under a current grant.

Applications for competing supplements are accepted on regular receipt dates and are reviewed in the same way as any other competing application. For more information about processing unsolicited investigator-initiated applications, including applications for competing supplements, see Receipt and Review of Unsolicited Applications.

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Non-Competing Continuation Grants

For each budget period within a previously approved project period (e.g., one year in a five-year grant), the investigator must submit an application to continue the grant.

In most cases, applicants may apply for out-year funding using the Streamlined Noncompeting Award Process (SNAP). Under SNAP, the GMO negotiates the direct costs for the entire competitive segment at the time of the competing award. This one-time negotiation eliminates the need for annual budget submissions and negotiations, simplifies the review of continuation applications, and reduces the complexity of monitoring grants.

For information about submission requirements for applications to be reviewed in the SNAP process, see http://grants.nih.gov/grants/policy/nihgps/part_ii_5.htm#noncontawards.

Applicants for non-competing continuation grants who have not established out-year funding agreements through SNAP must follow the procedures specified below.

Submission Requirements

To apply for a non-competitive continuation grant outside the SNAP process, the applicant must submit the Application for Continuation of a Grant (PHS Form 2590) or equivalent documentation. Applications must contain a progress report, an updated budget, and any other information required by the IC.

Approximately four months before the end of the current award, the Office of Policy for Extramural Research Administration (OPERA) will send the grantee a computer-generated face page and the required mailing labels. Applicants should use these materials to prepare and submit their applications.

Unless told otherwise by NCI staff, applicants must send their applications directly to the IC GMO at least two months before the beginning date of the next budget period.

Late submissions will delay the issuance of awards and may result in a reduction in the amount of the award.

Review of Applications

In the review process for non-competing continuation applications, the PD:

1. Receives the application and the Grant Documentation Control Form (i.e., the green sheet) for non-competing continuations from GAB.

2. Completes the Grant Control Form as indicated in the following section, specifying any additions or changes to the Notice of Grant Award on the back of the green sheet.

   If intramural investigators have been added to the project, the PD must consider whether the grant should be converted to a cooperative agreement. For information about this process, see Converting Grants to Cooperative Agreements.

3. Makes a copy of the signed green sheet for his or her records and transmits the completed form to GAB, authorizing GAB to issue the award.

Green Sheets

Follow the steps below to complete the green sheet for applications for non-competing continuation grants.

1. Human Subjects

    a. If applicable, enter the exemption number.

    b. If new performance sites have been added, ensure that approved assurances for each site are on file.

    c. Enter Yes or No to indicate whether the research protocol has changed since the last budget period.

    If Yes, indicate whether the new protocol is within the scope of the approved objectives. For information about the kinds of changes that would constitute a change in scope, see Item 4 below.

    d. Determine whether the type of research described in the application is exempt from tracking patient recruitment or the recruitment of women and members of minority groups.

    If the research is exempt, enter the appropriate Exception Code from the list on the back of the green sheet. If the Exception Code was 00 during the previous budget period, a gender/minority table should be completed.

    If the research is not exempt, review the application for compliance with NIH policy regarding the inclusion of women and members of minority groups in federally funded research.

    If the accrual of women and minority groups is inconsistent with NIH policy, request a recruitment plan from the applicant and notify the grants management specialist (GMS) that the approval of the application will be delayed until the applicant submits a recruitment plan.

    e. Indicate that the plan for including children in the research is coded as acceptable (A) on the summary sheet. If the application was originally coded as unacceptable (U), ensure that the problem identified by the SRG has been resolved before proceeding.

    f. Check Yes or No to indicate whether the research proposed in the application is eligible for a Certificate of Confidentiality.

g. Check Yes or No to indicate whether the research proposed in the application involves Phase I or Phase II clinical trials.

   If Yes, indicate whether data and safety monitoring (DSM) will be performed by NCI or a designee.

   If No, indicate whether a DSMP has been submitted. If submitted, indicate whether it has been approved.

   Specify the date on which the DSMP was requested.

h. Check Yes or No to indicate whether the research proposed in the application involves Phase III clinical trials.

   If Yes, indicate whether the membership of the DSMB has been approved by the relevant NCI division director or a designee.

2. Vertebrate Animals

   a. If new performance sites have been added, ensure that approved assurances for each site are on file.

   b. Check Yes or No to indicate whether the research protocol has changed since the last budget period.

      If Yes, indicate whether the new protocol is within the scope of the approved objectives. See Item 4 below, information about the kinds of changes that would constitute a change in scope.

4. Scope of Research

   Check Yes or No to indicate whether the scope of the research has changed since the previous budget period.

   The investigator may change the methodology, approach, or other aspects of the project objectives. However, the grantee must obtain approval from NIH for changes in scope, direction, type of training, or other areas that constitute a significant change from the aims, objectives, or purposes of the approved project.

   Changes likely to be considered a change in scope are:

- A change in the specific aims approved at the time of the award.

- Substitution of one animal model for another.

- Any change from the approved use of animals or human subjects.

- The use of a new technology, e.g., changing assays from those approved to a third party through a consortium agreement.

- The transfer of substantive work to a third party through a consortium agreement, by contract, or by any other means.
Such actions must always be approved by NIH for any application not subject to Expanded Authorities.

- A change in key personnel whose expertise was critical to the approved project.

- Significant rebudgeting, whether or not the particular expenditure(s) require approval under the rules governing changes in project budgets.
"Significant rebudgeting" would involve a change of more than 25% in a single direct cost budget category from the amount specified for that category in the budget agreed to at the beginning of the award period.

- Accrual of costs for patient care in a project for which the approved application did not specify patient care as a budget category.

- The transfer of funds into or out of the patient care category.

6. Foreign Application

   If new foreign sites have been added, complete an NIH Form 1820 and send it to the Fogarty International Center.

7. Cooperative Agreements

   Submit to GAB a memo describing the interactions of NCI/NIH staff and the investigator. Relevant interactions include meetings, resources provided and so on.

   Update the Terms of Cooperation.

8. Program Director

   Indicate whether a change in Program Director has occurred.

9. Approval of Changes in Scope or Objectives

   If changes in scope or objectives of the research are proposed for the continuation period (See Item 4 above.), indicate whether those changes have been approved.

10. Minority Supplements
    Indicate whether progress is acceptable.

11. Scientific Progress

    Indicate whether progress toward the aims of the project is satisfactory. If the report on activities during the previous budget period does not indicate satisfactory progress, contact the investigator to discuss the issue and to determine whether additional information that might reveal satisfactory progress is available. If no such information is available, see Enforcement Actions to identify an appropriate response.

Enforcement Actions

If a grantee has failed to comply with the terms and conditions of an award, NIH may take one or more enforcement actions. Such actions depend on the severity and duration of the noncompliance. The appropriate action will be determined after review of the annual progress report and consultation between members of the program staff and the grants management staff.

Enforcement actions include:

- Modification of the terms of the award.

  The awarding office may impose special conditions that require the grantee to correct financial or administrative deficiencies. The IC has the discretion to modify the terms of an award by imposing special conditions, by withdrawing approval of the investigator or other key personnel, or other actions.

- Suspension, termination, or withholding of support.

  The awarding office or the IC may suspend the grant pending corrective action or may terminate the grant for cause. Or, the awarding office may withhold the grant.

  Withholding a grant means that the awarding office has decided not to make a non-competing continuation award for the next budget period. A grant may be withheld if:

  - A grantee is delinquent in submitting required reports.

  - A grantee failed to show satisfactory progress in achieving the objectives of the project.

  - A grantee failed to meet the terms of a previous award.

  - A grantee failed to provide adequate stewardship of federal funds.

  - Continued funding would not be in the best interest of the government.

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Dissemination of Research Results

In keeping with the idea that NIH acts as an agent of the American people in distributing research funds, grantees are required to acknowledge public support for their work and to make the knowledge they have generated available to the public.

Publications – Acknowledgment of Federal Funding

All grantees must acknowledge federal funding when issuing statements, press releases, requests for proposals, bid solicitations, and other documents in which projects funded in whole or in part are described.

Grantees are required to state the percentage and dollar amounts of the total program or project costs financed with federal funds, as well as the percentage and dollar amount of the total costs financed by non-federal sources.

If an investigator fails to acknowledge federal funding, the PD should remind the investigator of the agreement regarding acknowledgment of federal funding established when the award was issued.

For more information about the publication of research findings, see http://grants.nih.gov/grants/policy/nihgps/part_ii_2.htm#fedfund.

Unique Research Resources

NIH policy requires that the results and accomplishments of the activities it funds be made available to the public. However, NIH recognizes that certain research findings may result in inventions. Grantees have the prerogative to protect these inventions, as long as they abide by the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR 401.

These regulations require the grantee to use patent and licensing processes to transfer grant-supported technology to industry for development. Alternatively, technology transfer may take place in the form of journal articles or other publications or through the availability of research products or resources.

Investigators are always encouraged to share reagents generated with federal funds, but decisions about whether a particular investigator must do so may be made on a case-by-case basis.

For more information about distributing or publishing unique research resources, see http://grants.nih.gov/grants/policy/nihgps/part_ii_5.htm#availofrr or http://www.nih.gov/od/ott/RTguide_final.htm.

Reporting Gender and Minority Accrual to Population Tracking Database

NIH policy requires that women and members of minority groups and their subpopulations be included in all NIH-supported biomedical and behavioral research involving human subjects, unless a clear and compelling rationale establishes that including such individuals is inappropriate with respect to the health of the potential subjects or the purpose of the research.

To insure that this requirement is met, investigators are required to provide information about the gender and ethnic composition of participant groups, and PDs are required to record the data reported in the NIH Population Tracking Database (also called the EZ Accrual Database).

For information about exceptions to these requirements, see Entering Data into the Population Tracking Database.

Reporting Requirements

For all grants coded 00, PIs are required to provide information about the anticipated composition of participant groups and their plans for recruiting women and members of minority groups when applications are first submitted. They are also required to report the actual composition of participant groups when submitting applications for noncompeting renewals (i.e., Type 5 applications).

If the application proposes more than one clinical study, each study must be reported separately. Reporting requirements are specified in the NIH Guide and are available online at http://grants.nih.gov/grants/guide/notice-files/not94-100.html. Applicants should be directed to use the Gender/Minority Accrual Tables in Form 2590 to present the required data.

Entering Data into the Population Tracking Database

PDs must enter the data regarding the regarding the gender and ethnic composition of participant groups reported by PIs in the EZ Accrual Database.

If the required data are not submitted with the noncompeting renewal application, the PD must send a request to the investigator indicating that the data must be provided before a renewal application can be funded. The letter should indicate that, if more than one clinical study has been conducted or is in progress, the accrual data for each study must be reported separately.

For Phase I clinical trials, investigators are not required to report the anticipated composition of participant groups. Further, research involving human subjects may be exempt from the reporting requirements described above if the research falls within certain categories. These categories and the related exemption codes are listed on the back of the control sheet (i.e., the green sheet). Only grants coded "00" on the green sheet are tracked in the database.

PDs should note that the exemption code associated with the original application may not apply if clinical studies have been completed when applications for noncompeting renewal grants are submitted.

The EZ Accrual Database is available at http://cii.nci.nih.gov. For instructions on entering population tracking data, contact your Divisional Representative.

Name	Organization	Phone	Email
Margaret Holmes	ODDES	496-4995	holmesm@mail.nih.gov
Ann Carpenter	CTD	402-0427	carpentera@ctep.nci.nih.gov
Diane Bronzert	DEA	435-5655	bronzerd@mail.nih.gov
Cynthia Whitman	DCP	496-0276	whitmanc@main.nih.gov
Lora Kutkat	DCP	594-7635	kutkatl@mail.nih.gov
Everett Carpenter	DCCPS	435-8637	carpenter@mail.nih.gov
Mark Alexander	DCCPS	435-8335	alexandm@mail.nih.gov
Marianne Henderson	DCEG	496-8672	hendersm@mail.nih.gov
Ronald Thayer	CCR	435-4003	thayerr@mail.nih.gov

Updating CRISP Abstracts

CRISP, which stands for Computer Retrieval of Information on Specific Projects, is a database that contains information about biomedical research grants and contracts funded by NIH. Members of the Center for Scientific Review staff enter the abstract and project description for every funded grant and contract into CRISP within two months of the time an award is made.

This information is made available to the public though the NIH website and is used by various NIH offices to track NIH investments in particular research areas. Within NCI, EFDB, the Research Analysis and Evaluation Branch of DEA, and the Scientific Information System draw on the information stored in CRISP to carry out their work.

The Office of Extramural Research requires that all ICs provide up-to-date abstracts, reflecting budget cuts made in the review and funding process for multi-project applications.

PDs must enter these data into CRISP following the NCAB review of applications. Instructions for updating abstracts are available at http://deaintranet.nci.nih.gov/ncipolicy/crisp_abstracts.htm.

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Change of Principal Investigator or Institution

Inevitably, circumstances will arise in which the commitments of the key personnel named in a grant application change. People take new jobs, move to new cities, or become interested in other projects. Similarly, PIs may move to new institutions.

As applications are funded based on the specific commitments of key personnel and as grants are issued to institutions rather than to individuals, these changes must be reported to the awarding IC and the PD who is managing the grant. The PD must inform investigators and institutions about NCI policies that affect their rights and responsibilities in such situations.

Change of Principal Investigator or Other Key Personnel

Grantees are required to notify NIH about changes in the commitments of key personnel approved at the time of the award. Such notices are required if the PI or other key personnel intend to withdraw, be absent from the project for a continuous period of three or more months, or reduce the amount of time devoted to the project by 25% or more.

If such changes in personnel occur or are anticipated, grantees must notify NIH and request approval of an alternate arrangement. Such an arrangement may involve replacement of the PI or other key personnel. The request for approval must include a justification for the change, the curriculum vitae of new personnel, and any budget changes resulting from the proposed change.

If the arrangements proposed by the grantee or the qualifications of any individual proposed as a replacement are not acceptable to NIH, the grant may be suspended or terminated.

If the grantee is unable to make alternate arrangements that reflect changes in the commitments of key personnel, he or she may wish to terminate the project. In such cases, the grantee must notify the awarding Grants Management Office, in writing, of its wish to terminate, and NIH will forward closeout instructions.

Change of Grantee Organization

If a grantee wishes to transfer legal and administrative responsibility for a grant-supported project from one legal entity to another, the grantee must obtain NIH approval before the expiration date of the approved project period.

Such a change of grantee organization may be accomplished under most NIH grants, including construction grants, if:

- The grant to be transferred has been terminated in accordance with 45 CFR 74.61 or 92.43.
- A non-competing continuation award is withheld within an approved project period because of the actions of the grantee.
- The original grantee has agreed to relinquish responsibility for an active project before the expiration of the approved project period.

  Grantee organizations may relinquish responsibility for projects if the PI moves from one domestic organization to another or from a foreign organization to a domestic organization.

  The project may be supported at a new organization for a period up to the remainder of the previously approved project period in an amount not to exceed that previously recommended for direct costs (plus applicable F&A costs) for the remaining period.
- Changes of grantee organization that would involve the transfer of a grant from a domestic organization to or from a foreign organization or an international organization are not permitted.

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Extension or Submission of Renewal Applications

If the work specified in an approved research plan is not finished when the project period ends, investigators may wish to extend the period of the grant, even if no supplemental funds are required or available. Or, investigators may want to seek renewal grants to continue their work.

Extensions for Grants Awarded under Expanded Authorities (SNAP)

For grants awarded under Expanded Authorities, which includes all R grants (except SBIR/STTR) and P01 grants, the grantee may extend the final budget period without approval from NIH for up to 12 months beyond the expiration specified in the Notice of Grant Award.

Such extensions are possible if (1) no additional funds are required and (2) there will be no change in the project's originally approved scope or objectives, and (3) any one of the following applies:

- Additional time beyond the established expiration date is required to ensure that the originally approved project can be completed.
- Continuity of NIH grant support is required while a competing continuation application is under review.
- Additional time is needed to permit an orderly phase-out of a project that will not receive continued support.

The fact that funds remain at the expiration of the grant is not, in itself, sufficient justification for an extension without additional funds. The grantee must notify the NIH awarding office, in writing, of the extension 10 days before the expiration date of the project period.

Grantees may not extend project periods previously extended by the NIH awarding office. Any additional extension beyond the one-time extension of up to 12 months requires NIH prior approval.

For more information, see http://odoerdb2.od.nih.gob/gmac/nihgps/part_ii_5.htm#expandauth.

Extensions for Grants Not Covered by Expanded Authorities

A request for a non-competing extension of the project period for a non-SNAP grant should be submitted to the IC GMO, in writing, at least 30 days before the project period will expire.

Such requests are typically submitted when more time than was specified in the approved application is needed to:

- Provide continuity of project activities while a competing continuation application is under review.
- Permit orderly phase-out of project activities for which there will be no further NIH support.

Investigators may request a small amount of money for either of these purposes, or may simply request more time. Extensions of up to 12 months are generally permitted.

The request must:

- Specify the new ending date that is being proposed.
- Include justification for the extension.
- Report the amount of money remaining from the approved budget and indicate how that money will be used.

The application letter must be co-signed by an institutional business official.

For an extension that would exceed 12 months, special justification is required.

For more information about NIH policies on extensions, see
http://www3.od.nih.gov/oma/manualchapters/grants/4801.htm and
http://odoerdb2.od.nih.gov/gmac/nihgps/part_ii_5.htm#priorapp.

Submission of Renewal or Competitive Grant Applications

Instructions for submission of competitive grant applications are provided in the PHS398 grant application instructions:

- The R01 competitive renewal application receipt dates are March 1, July 1, and November 1.
- The receipt dates for new and competitive renewal of P01 applications are February 1, June 1, and October 1.

Competing Continuation Grants Submitted in Response to RFAs

Unless otherwise specified in the RFA at the time of the original competition, and if no further direct programmatic involvement is required, competing continuations of such awards must be through general unsolicited, non-cooperative agreement RPG mechanisms (R01s, P01s, and so on).

Competing Continuation Cooperative Agreement Applications

In certain cases, NCI may permit selected or self-designated single competing applications for the continuation of an existing cooperative agreement. If such circumstances, a new RFA is not required. Ordinarily, an ad hoc committee within DEA would be appointed to review the application.

However, because there was no explicit commitment to renewal within the original RFA, PDs must obtain single-project concept approval from the EC before such an application can be considered. PDs should inform potential applicants of this requirement early in any discussion of the idea of continuing the agreement.

For more information about continuing cooperative agreements, see NCI Policies online at http://deaintranet.nci.nih.gov/ncipolicy/RFAtype2.htm.

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Termination and Closeout

Unless an extension is granted by the GMO, grantees are required to submit a final financial and progress report within 90 days of the end of the period of a grant.

The final progress report should include:

- A summary of progress toward the achievement of the originally stated aims.
- A list of significant results.
- A list of publications.

If a competitive renewal (Type 2 R01) has been submitted, whether funded or not, the progress report contained in

that application may be submitted as the final progress report.

Procedures for Closing Out Grants

The procedures for closing out a grant are as follows:

1. GAB sends a request for the information required to close out the grant to the institutional business official and sends a copy of the request to the PI.

   Institutions must submit final reports promptly. After a delay of 150 calendar days, official sanctions may be invoked. For a description of these sanctions, see http://www3.od.nih.gov/oma/manualchapters/grants/5805/main.html.

2. GAB sends a copy of the final report, along with a sign-off sheet, to the PD who administered the grant.

3. The PD reviews the final report. If the report meets, NIH requirements, the PD signs off, and returns the sign-off sheet to GAB, where a copy is kept in the official file.

Before closing a grant file, GAB will ensure that the file contains all the documents associated with the grant–from the initial application to the final report.

For information about closing out grants issued under specific funding mechanisms, see the NIH Policy Manual 5805.

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Responding to Inquiries about NCI Projects and Policies

Requests for information about NCI projects and policies arise frequently. Such requests may come from members of the public, from the press, from members or Congress, or Executive Branch officials.

To respond to these requests, NCI has established specific offices or has assigned responsibility for responding to certain kinds of inquiries to NCI offices with broader responsibilities. PDs may direct questions to these offices and may also be asked to respond to requests for information by the staff in these offices.

NCI Office of Cancer Communication

The Office of Cancer Communication (OCC) serves as a triage center, responding to or referring inquiries about cancer and NCI programs to appropriate sources of information.

Such sources include the Cancer Information Service, the Legislative Office, the Press Office, the Office of Liaison Activities, NCI publications, and NCI websites.

The OCC provides:

- Quick responses to requests for information from the Executive Branch, Congress, and other parts of the government.
- Responses to requests for information from the press and the public.
- Oversight of correspondence and fact sheets that describe NCI policies and programs.
- Oversight of responses to inquiries resulting from NCI public affairs programs.

For information about OCC services or to obtain advice about responding to an inquiry, contact:

Office of Cancer Communications
National Cancer Institute
Building 31, Room 10A29
Bethesda, MD
301-496-6631

http://dino.nci.nih.gov/admin/occ/RESPON.HTM

http://dino.nci.nih.gov/admin/occ/MEDREL.HTM

NCI Office of Legislative and Congressional Activities

he Office of Legislative and Congressional Activities responds to requests for information from members of Congress. This office contacts ARC managers for information about particular grants, and the ARC manager contacts the relevant members of the program staff.

NCI Privacy Act/Freedom of Information Act Office

Requests for information covered by the Privacy Act or the Freedom of Information act should be referred to:

NCI FOIA and Privacy Act Coordinator
Freedom of Information/ Privacy Act Office
Federal Building, Suite 302
7550 Wisconsin Avenue, MSC 9009
Bethesda, MD 20892
Phone: 301-496-2999
Fax: 301-435-2931

http://cancer.gov/legis/foiacoordinator.html

NCI Grants Operations Section, GAB

The Grants Operations Section within GAB responds to Freedom of Information and Privacy Act inquiries about grants. Requests for such information should be referred to:

Don Courtney
Grants Operation Section
Grants Administration Branch
National Cancer Institute
Bethesda, MD 20892
Phone: 301-496-8790
Fax: 301-496-8601

http://www.nci.nih.gov/admin/gab/sections.htm#gos

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Addressing Allegations of Scientific Misconduct

This section describes NCI policies on scientific misconduct and specifies the roles and responsibilities of federal offices that deal with various aspects of scientific misconduct.

NCI Policies on Scientific Misconduct

According to the NIH Grants Policy Statement (effective for budget periods beginning October 1, 1998), "the grantee will inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent misconduct in science." That is, responsibility for ensuring the ethical execution of NCI-funded research and for managing the funds awarded by NCI appropriately rests squarely with the grantee organization. The following paragraphs contain detailed descriptions of these responsibilities.

Regulations at 42 CFR Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science," specify grantee responsibilities in dealing with and reporting possible misconduct in science.

Organizations applying for or receiving NIH research grants are required to certify in their applications that they have established administrative policies as required by 42 CFR 50, Subpart A, and will comply with those policies and the requirements of the regulations. The regulations are available on the Office of Research Integrity (ORI) website at http://ori.dhhs.gov.

The primary responsibility for ensuring that an NIH-funded project is being conducted in accord with the approved application and budget and the terms and conditions of the award rests with the grantee. These responsibilities must be carried out with extra care where misconduct in science has been found or where a misconduct-in-science

investigation has been initiated, as specified in 42 CFR 50.103 and 50.104.

The grantee shall report promptly to ORI any incident of alleged or apparent misconduct in science that warrants investigation and must advise ORI of any decision to initiate an investigation. The regulations also require that the institution submit an Annual Report on Possible Research Misconduct to ORI to maintain their assurance.

Where a misconduct investigation has been initiated, the grantee must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project(s), protect human subjects and animals, provide reports to ORI, and ensure the proper expenditure of funds and continuation of the project during the conduct of the investigation, if appropriate.

The ORI staff assists grantees with misconduct-in-science investigations and reporting, and IC staff members may provide technical assistance and work jointly with grantees to protect funded projects from the adverse effects of misconduct in science.

When a finding of misconduct in science has been made regarding conduct by an individual working on an NIH grant-supported project, the grantee must assess the effect of that finding on the ability to continue that project, as originally approved by NIH, and promptly obtain NIH approval of any intended change of PI or other key personnel.

A finding of misconduct in science may result in a range of possible sanctions by NIH, including, but not limited to:

- Withdrawal of approval of the PI or other key personnel.
- Debarment.
- Disallowance of costs associated with the invalid or unreliable research.
- Withholding of all or part of a continuation award.
- Suspension or termination, in whole or in part, of the current award.

For more information about these sanctions, see http://grants.nih.gov/grants/policy/nihgps/part_ii_7.htm#enforcement.

The grantee is responsible for the actions of its employees and other research collaborators involved in the project. Where the validity or reliability of data has been affected by misconduct in science, the grantee and employee/collaborator authors are responsible for submitting a correction or retraction of the data to a journal, as appropriate, and/or publishing the corrected data, if required.

ORI or NIH may require corrections or retractions. If the grantee does not comply with this requirement, NIH may invoke its rights, under 45 CFR Part 74 or 92 to:

- Obtain access to the data, including copyrightable material developed under the award.
- Have the data reviewed.
- Submit the correction to the organization that published the original data

Issues involving potential criminal violations, such as misappropriation of federal funds, must be promptly reported

to the DHHS Office of the Inspector General.

Federal Offices with Responsibilities for Responding to Scientific Misconduct

There are several agencies and offices concerned with investigating and responding to scientific misconduct. Which of these units is responsible depends on the kind of misconduct involved in a specific case. They include:

The DHHS Office of Research Integrity

The DHHS Office of Research Integrity (ORI) is responsible for protecting the integrity of PHS extramural and intramural research programs. ORI oversees and directs the Public Health Service (PHS) research integrity effort, with the exception of the regulatory research activities of the Food and Drug Administration. For more information, see the ORI website at http://ori.dhhs.gov.

The DHHS Office of Human Research Protections

The DHHS Office of Human Research Protections is responsible for responding to allegations of misuse of human and animal subjects in research supported by DHHS. Allegations in this area may involve:

- Improper care of research animals.
- Failure to obtain informed consent from human subjects.
- Mistreatment of human or animal subjects in research.
- Failure to obtain approval from an institutional review board or animal care committee.

For more information, call OHRP at 301-496-7005 or see http://ohrp.osophs.dhhs.gov/.

The Food and Drug Administration

Allegations of misconduct in regulated research monitored by the Food and Drug Administration (FDA) are generally investigated by:

The Office of Regulatory Affairs
Division of Compliance Policy
Bioresearch Program Coordination
FDA. Contact James F. McCormack, Ph.D., Office of Enforcement/Division of Compliance Policy, at (301-) 827-0425.

This agency focuses on testing and evaluating human and animal drugs, food and feed additives, and human biological products and medical devices.

ORI may also take actions related to FDA-regulated research if the research is also supported by PHS grants, cooperative agreements, or contracts.

The NIH Office of Management Assessment and Internal Control

The NIH Office of Management Assessment and Internal Control (OMAIC) handles allegations of fraud or financial mismanagement of NIH research funding. Allegations in this area involve using research funds for unauthorized purposes and/or the submission of false expenditure claims.

If a direct response is required, contact OMAIC at 301-496-1873.

In cases where large sums of money may be at risk due to fraud, mismanagement, or waste, the Office of the Inspector General may be involved. This office can be contacted at 301-402-0930.

Normally, the types of allegations outlined above should be discussed first with the relevant NCI grants or contracts administration staff at 301-496-8628.

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NCI Initiatives

Launching Research Enterprises through NCI Initiatives

- Soliciting Applications for New Research: RFAs and PAs
  - Description of Requests for Applications (RFAs)
  - Description of Program Announcements (PAs)
- Soliciting Applications from Current Grantees
- Soliciting Applications for Technology Research (R21and R33)

Locating Policies and Procedures

- Locating NIH Policies on Research Initiatives
- Locating Information Resources for the Development of NCI Initiatives

Preparing Research Initiatives

- Obtaining Approval to Issue an RFA
  - Concept Approval
  - Approval of the Content of the RFA
  - Approval to Reissue RFAs
  - Advising Grantees about Obtaining New Support When an RFA Expires

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Launching Research Enterprises through NCI Initiatives

To stimulate new research in particular areas, NCI program staff may issue:

- Requests for Applications (RFAs).
- Program Announcements (PAs).

To provide continuing support for current grantees, NCI program staff may issue:·

- Limited competition solicitations (also called Letter RFAs).
- Administrative supplement solicitations.

To support technological innovation, NCI funds:

- Grants for preliminary exploratory/developmental work under the R21 mechanism.
- Grants for advanced exploratory/developmental work under the R33 mechanism.

Soliciting Applications for New Research: RFAs and PAs

To solicit applications for research in new areas or to rekindle research activity in a particular area, NCI issues Requests for Applications (RFAs) and (PAs). These notices must be published in the NIH Guide.

Description of Requests for Applications (RFAs)

An RFA is a formal statement that invites applications for grants or cooperative agreements in a well-defined scientific area to accomplish specific program objectives. Through RFAs, NCI can:

- Encourage investigators to enter new research domains or address gaps in the current state of knowledge about a particular topic.
- Provide resources to reduce technical barriers to progress in specific research areas.
- Facilitate the development of research resources.
- Support multidisciplinary interactions.
- Respond to congressional mandates to pursue certain research goals.

Special funds are allocated to support the initiative, and, in most cases, a special Scientific Review Group (SRG) is convened by the Institute or Center (IC) that issued the RFA to review applications. An RFA, therefore, communicates a clear interest on the part of NCI in supporting certain scientific endeavors.

Description of Program Announcements (PAs)

A PA is a formal statement identifying a new research area that NCI wishes to support or an area in which NCI hopes to rekindle research activity. A PA differs from an RFA in that:

- PAs do not generally entail the financial and administrative commitments (i.e., special funds, special review panels) associated with RFAs.
- The review and administration of applications submitted in response to a PA are handled through usual NCI channels.

To strengthen the appeal of PAs, program staff may, if authorized, use one of two variations on the usual structure of a PA. These variations include:

- Program announcements with specific referral (PARs).

  A PAR specifies that applications will automatically be referred to the NCI Division of Extramural Activities (DEA). In issuing the PAR, members of the program staff may want to consider establishing a single receipt date and convening a special panel to review applications submitted in response to the RFA. As with other aspects of the initiative, these features must be approved by the relevant NCI official.

- Program announcements with set-aside funds (PAS).

A PAS indicates that funds will be set aside to support research proposed in response to the announcement. The availability of a special fund to support the initiative signals NCI's interest in the research area to the scientific community.

Soliciting Applications from Current Grantees

In most instances, NIH policy requires open competition for research funds. In certain circumstances, however, inviting applications from current grantees may be justified.

- Limited competition solicitations (Letter RFAs) may be permitted when:

  - Additional investment is required to carry out current projects. For example, funds may be required to complete a clinical trial.

  -Additional investment is justified by the uniqueness of particular research enterprises. For example, a researcher may have access to a familial cohort that provides a rare opportunity to examine the genetics of a particular form of cancer.

- Administrative supplements may be used to invite applications for funds to cover expenses that arise in the execution of research within the scope of an existing award.

Soliciting Applications for Technology Research (R21 and R33)

NCI developed the Phased Innovation Award and the Phased Technology Award to foster the translation of emerging technologies from pilot research to research development, speeding the adoption of near-term technological opportunities. Notices about the availability of these awards are published in the NIH Guide.

Both awards involve (a) support for early research regarding a specific technology under the R21 mechanism and (b) support for more advanced research about the technology under the R33 mechanism.

The Phased Innovation Award supports:

- Feasibility studies through the R21 mechanism.
- Full-scale technology development using the R33 mechanism.

The Phased Technology Application Award supports:

- Evaluations of the utility of new technologies through the R21 mechanism.
- Pilot studies of the application of new technologies in cancer research using the R33 mechanism

Special features of these awards include:

- Minimal or no funding gap between the feasibility and development phases based on the accomplishment of negotiated scientific milestones. (Need link to Chapter 7 here.)
- Flexible timing of feasibility and development phases.
- Flexible budget structure.

Decisions as to whether to fund follow-on R33 applications depend on program priorities, the availability of funds, and the applicant's success in attaining the milestones specified in the R21 application.

NCI program staff coordinate the review of the progress made during the R21 phase. The type of review depends on the complexity of the milestones and the size of the proposed funding increase.The policy for approval of the transition from the R21 phase to the R33 phase and the letter to grantees is available at http://deaintranet.nci.nih.gov:80/ncipolicy.

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Locating Policies and Procedures

Both NIH and NCI specify policies and procedures for the development and approval of RFAs and PAs. Most of these information resources are available online.

Locating NIH Policies on Research Initiatives

To obtain information about NIH and NCI policies on research initiatives, consult:

- NIH Manual Chapter 4110 - Program Announcements and Requests for Applications.

  This chapter describes procedures for the initiation, development, clearance, publication, and dissemination of RFAs and PAs. For an online version of this chapter, see http://www3.od.nih.gov/oma/manualchapters/grants/4110.htm.

- NIH Manual Chapter 4815 - Implementation of Cooperative Agreements.

  This chapter contains policy and procedures for the implementation of cooperative agreements. For an online version on this chapter, see http://www3.od.nih.gov/oma/manualchapters/management/1820.

- NIH Manual Chapter 1820 - Selection of Extramural Award Instrument: Grant, Cooperative Agreement, or Contract

  This chapter provides guidance on selecting the appropriate award instrument for conducting extramural research, development, and training, activities. For an online version of this chapter, see http://www3.od.nih.gov/oma/manualchapters/management/1820/.

Locating InformationResources for the Development of NCI Initiatives

To obtain information relevant to the development of research initiatives, consult:

- The RFA Evaluation Committee Report (December 12, 1997).

  The RFA Evaluation Committee was charged with evaluating the RFA as a mechanism for advancing NCI's scientific goals. The Committee examined the strategic value of RFAs, and also addressed the preparation, approval and clearance of RFAs. For an online version of the Committee's report, see http://deaintranet.nci.nih.gov/dea/rfa/reports/evaluation.htm.

- The Early Notification System.

  The Early Notification System (ENS) is designed to provide a "heads up" about RFAs and PAs from all ICs to all NIH staff before they are issued. To view the ENS database, see http://odoerdb2.od.nih.gov/cfdocs/ens/ens_main.cfm.

ENs relevant to NCI staff are sent to NCI divisional representatives by email, and are subsequently forwarded to PDs in program areas relevant to the topic of the RFA or PA discussed in the notice. Policies and procedures for NCI participation in initiatives generated by other ICs are posted at http://deaintranet.nci.nih.gov/rfaindex.htm.

To obtain information about NCI policies for expedited handling of initiatives generated by other ICs, see http://deaintranet.nci.nih.gov:80/ncipolicy/rfa-pa_clearance.htm.

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Preparing Research Initiatives

NCI provides several resources to assist PDs in the preparation of research initiatives. These resources include:

- A timeline specifying each of the steps required and the dates at which these steps must be carried out to

ensure that the initiative is published on the desired date. This timeline is available at http://deaintranet.nci.nih.gov/rfaindex.htm.

- Templates that specify the structure and contents of the documents required in the approval process. PDs must use these templates to create the documents required to obtain approval for a research initiative. These templates are all available online.

  -For the RFA Request for Concept Approval form, see http://deaintranet.nci.nih.gov:80/dea/rfa/concept_approval_form.htm.

  - For instructions regarding the justification narrative required for RFAs, see http://deaintranet.nci.nih.gov:80/dea/rfa/narrative_justy_4_rfa-pa.htm.

  - For RFA templates, including cooperative agreements, see http://deaintranet.nci.nih.gov:80/dea/rfa/rfalish.htm and http://www3.od.nih.gov/oma/manualchapters/management/1820.

  - For PA templates, including PARs, see http://deaintranet.nci.nih.gov:80/dea/pa/palist.htm.

  - For limited competition (Letter RFA) templates, see http://deaintranet.nci.nih.gov:80/forms/rfa_limcomp.htm.

Obtaining Approval to Issue an RFA

When published, the RFA must specify:

- The goals of the initiative and the criteria against which applications will be reviewed.
- The estimated amount of the funds set aside for the program.
- The estimated number of awards to be made.
- The deadline for the submission of applications.

Obtaining approval to issue RFAs involves first obtaining approval of the concept and then obtaining approval of the full text of the RFA.

Concept Approval

The concept to be addressed in the RFA must be approved by the division director and the Executive Committee (EC). New RFAs must also be approved by the Board of Scientific Advisors.

The procedure for obtaining EC approval of the concept is as follows:

1. The PD presents the idea for the RFA to the division director.

2. The division director approves the idea.

3. The PD contacts the Executive Secretary of the Executive Committee (EC) to schedule a time to present the idea to the EC at the regularly scheduled concept meetings. These meetings are held three times each year. To find the dates of these meetings, see http://deaintranet.nci.nih.gov/rfaindex.htm.For cooperative agreements only, the PD contacts the Chief of the Research Contracts Branch (RCB) to obtain approval to issue the RFA as a cooperative agreement.

4. The PD prepares a Request for Concept Approval form and submits it to the Executive Committee.

5. The EC approves the request. For RFA renewals, the EC also determines whether BSA approval is required.

6. The PD contacts the Executive Secretary of the BSA to schedule a presentation of the idea at the next meeting of the BSA (BSA meetings are held three times each year, generally in March, June and November.) and sends the approved request to the Executive Secretary for distribution to the members of the BSA.

Approval of the Content of the RFA

After the BSA approves the concept:

1. The PD modifies the RFA draft based on the discussion of the BSA.

2a. The PD submits the draft RFA to the DEA RFA Officer.

2b. For cooperative agreements only, the PD also writes a memo of justification for the use of the cooperative agreement mechanism using a template provided by the RFA Officer and sends this memo to the RFA Officer.

2c. For cooperative agreements only, the PD submits the draft RFA to the Chief of RCB.

3. The RFA Officer coordinates the review of the draft RFA by the Grants Review Branch (GRB) and the Special Review and Resources Branch (SRRB).

4. The RFA Officer sends the comments of the GRB and the SRRB to the PD for final revisions.

5. For cooperative agreements only, the RFA sends the final RFA and the memo of justification to the NIH Office of Extramural Programs (OEP) for approval of the funding mechanism.

6. The PD and the RFA officer review the final text for compliance with NIH policies and procedures. For cooperative agreements, this review also involves responding to comments and suggestions for OEP.

7. The RFA Officer submits the RFA to the NIH Guide Office for publication.

8. The RFA is published in the NIH Guide. (The announcement should be published at least 90 days before the deadline for the receipt of applications.)

Approval to Reissue RFAs

Members of the program staff may want to reissue an RFA to support activities that have not been completed (e.g., clinical studies, technology development) or to support a consortium to pursue further research in the area. If restricting the submission of applications to current grantees can be justified, the RFA may be reissued as a limited competition RFA. For information about limited competition RFAs, see Soliciting Applications from Current Grantees.

The process of reissuing an RFA should be initiated about 15 months before the grants issued under the existing RFA expire. The timeline for obtaining approval to reissue the RFA is similar to the timeline for obtaining initial approval for RFAs. If the EC determines that the scope or work is substantially the same as that approved for the original RFA, approval by the BSA may not be required.

Advising Grantees about Obtaining New Support When an RFA Expires

As noted in Approval to Reissue RFAs, an RFA may be reissued. If, however, the RFA is not reissued, PDs may advise applicants to seek continued support under the funding mechanisms (R01, P01) for investigator-initiated research grants.

Cooperative agreements may not be submitted for renewal unless they are submitted in response to a specific RFA or PA. If a renewal application previously funded as an RFA cooperative agreement is submitted as an investigator-initiated competitive renewal under the R01 or P01 mechanism and the PD believes that continuing the activity as a cooperative agreement is warranted, the PD may request approval to convert the application/award to a cooperative agreement.

For information about converting investigator-initiated applications/award to cooperative agreements, see Converting Grants to Cooperative Agreements.

Obtaining Approval to Issue a PA

The process for obtaining approval of a PA differs from that of obtaining approval for an RFA in that:

- PAs do not require the approval of the Board of Scientific Advisors(BSA).
- PAs cannot be used to solicit applications for cooperative agreements.

Concept Approval

The concept to be addressed in the PA must be approved by the division director and the Executive Committee (EC).

The procedure for obtaining EC approval of the concept is as follows:

1. The PD presents the idea for the PA to the division director.
2. The division director approves the idea.
3. The PD contacts the Executive Secretary of the Executive Committee (EC) to schedule a time to present the idea to the EC.
4. The PD prepares a Request for Concept Approval form and submits it to the Executive Committee.
5. The EC approves the request.

Approval of the Content of the PA

After the concept of the PA has been approved:

1. The PD modifies the PA draft based on the discussion of the EC
2. The PD submits the draft PA to the RFA Officer
3. The RFA Officer coordinates the review of the draft PA by the Grants Review Branch (GRB) and the Special Review and Resources Branch (SRRB).

4. The RFA Officer sends the comments of the GRB and the SRRB to the PD for final revisions.

5. The PD and the RFA Officer review the final text for compliance with NIH policies and procedures.

6. The PD submits the PA to the NIH Guide Office for publication.

Approval to Reissue PAs

Program announcements issued by NCI remain active for two years from the date on which they were issued unless otherwise specified by the extramural division directors (EDD). Requests to reissue PAs are considered at a single meeting of the EDD in July of each year.

Three months before the meeting, the DEA Program Coordination and Referral Branch (PCRB) will contact the PD for all expiring PAs. If the division wishes to reissue the PA, PCRB helps to prepare the materials to be submitted to the EDD.

The full text of the policy is located at http://deaintranet.nci.nih.gov:80/dea/rfa/pa_expirationdate.htm.

Issuing Solicitations for Applications from Current Grantees

- Limited Competition Solicitations (Letter RFAs)

  To notify researchers who might compete for these awards, requests for limited competition applications should be published in the NIH Guide. These notices should contain a justification for the use of this funding mechanism.

- Administrative Supplement Solicitation

  Decisions as to whether to issue administrative supplements are made by NCI staff. Peer review is not required.

  Solicitations for administrative supplements require concept approval. Although publication of these solicitations is not required, they are typically published in the NIH Guide. Notices about the availability of administrative supplements are also distributed through listservs and displayed on websites.

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SBIR/STTR Programs

Providing NCI Support for R&D by Small Businesses

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are set-asides designed to provide an economic incentive for the small business community to undertake projects relevant to the goals of NCI. These programs were established by Congress, and are intended to:

- Stimulate technological innovation in the private sector.
- Strengthen the role of small business in meeting federal research and development needs.
- Increase the commercial application of federally supported research.
- Encourage technological innovation by socially and economically disadvantaged and woman-owned businesses.
- Foster cooperative research and development partnerships between small businesses and non-profit research institutions.

Applicants compete for funding, and award decisions are based on the outcome of peer reviews.

Information about NIH SBIR/STTR programs is available at http://grants.nih.gov/grants/funding/sbirsttr_sites.htm. The NCI SBIR/STTR program is coordinated through the Office of Technology and Industrial Relations. For information about these programs, see http://otir.cancer.gov/ir/small_biz.html.

The programs described in this chapter are mandated by Congress. In addition to participating in these programs, NCI supports the development and testing of new technologies through the Phased Innovation Award and the Phased Technology Award programs, which are funded under the R21/R33 mechanisms. For information about these programs, see Soliciting Applications for Technology Research (R21 and R33) or the Office of Technology and Industrial Relations website identified in the previous paragraph.

Meeting Eligibility Requirements

To be eligible for SBIR or STTR awards, organization must:

- Be at least 51% owned and independently operated by American citizens.
- Have no more than 500 employees.

- Be a for-profit US corporation.
- Be the primary employer of the principal investigator (SBIRs only).

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Soliciting Applications

Both NIH and NCI have special programs for soliciting applications for SBIR and STTR awards. In addition, PDs are encouraged to use information channels relevant to their programs to notify potential applicants about the availability of such funds.

Using Publications to Solicit Applications

NCI research priority areas are published annually in the "Omnibus Solicitation of the National Institutes of Health, Centers for Disease Control and Prevention, and Food and Drug Administration for Small Business Innovation Research and Small Business Technology Transfer."

Instructions for applicants and application forms are included in the solicitation book. The solicitation book is not issued in hardcopy, but it is available online at http://grants.nih.gov/grants/funding/sbirsttr1/index.pdf.

Using PARs and RFAs to Solicit Applications

The SBIR/STTR programs are important to NCI, but some SBIR/STTR projects require more flexibility in project budgets and duration than is consistent with statutory guidelines.

To support such projects, NCI uses PARs and RFAs to solicit applications from organizations that are eligible to receive grants under the criteria established by Congress. NCI also establishes contracts with eligible organizations. For more information about RFAs, PARs, and contracts in the context of SBIR, see Soliciting Applications for Technology Research (R21 and R33).

Using Outreach Activities to Solicit Applications

To encourage potential applicants to submit applications for SBIR/STTR awards, PDs and other NCI program staff should attend SBIR/STTR conferences to discuss the programs and notify for-profit organizations about the availability of R&D funds through SBIR/STTR programs.

In these discussions, PDs may:

- Define eligibility and feasibility criteria for applicant organizations and principal investigators.
- Advise potential applicants as to whether their project ideas are more compatible with the goals and guidelines of the SBIR program or with those of the STTR program.
- Explain the application and review process.
- Caution potential applicants about conflict of interest problems.

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Defining the Structure of SBIR and STTR Awards

SBIR and STTR awards are separated into three phases, with each phase depending on the success of the previous phase. Only the first and second phases are eligible for support through set-aside funds. Support for the third phase must come from private sources or from federal sources other than the funds set aside for SBIR/STTR programs.

The activities to be carried out in each phase are as follows:

- In Phase I, the business undertakes feasibility studies with the goal of providing proof of the technical merit of the R & D work proposed in its application.
- In Phase II, the business works to develop or improve its product. Phase II applications may be submitted at any time following the Phase I award.
- In Phase III, the business conducts any additional research that may be needed and commercializes its product.

The Fast Track program allows applicants to apply for Phase I and Phase II funding simultaneously.

Statutory guidelines govern the amount of money that can be awarded to SBIR/STTR applicants for Phase I and Phase II work and also specify the duration of each phase. Deviations from these guidelines are permitted but must be well justified.

The chart below specifies characteristics of and application requirements for Phase I and Phase II awards.

	SBIR	**STTR**
Phase I		
Total Cost*	$100,000	$100,000

Duration	Six months	One year
Collaboration**	33% of total cost	Minimum of 30% of total cost Maximum of 60% of total cost
Application Format - Budget = $100,000	Modular	Modular
- Budget > $100,000	Traditional	Traditional
Phase II		
Total Cost	$750,000	$500,000
Duration	Up to 24 months	Up to 24 months
Collaboration*	50% of total cost	Minimum of 30% of total cost
Application Format	Traditional	Traditional

* In general, Phase I awards are not to exceed $100,000, but if the project cannot reasonably be accomplished within this limitation, a larger budget may be requested. If the application is approved on merit and the additional funding is justified, larger budgets may be supported. As indicated in the preceding chart, applicants who are seeking more than $100,000 in research funds must submit traditional, rather than modular applications.

** For SBIR grants, collaboration refers to subcontracts, consultants and so on. For STTR grants, collaboration includes a well-defined partnership between the small business and a nonprofit research institution. This agreement must be specified in detail before the award is issued.

Specifying Requirements

Some special requirements apply to both SBIR and STTR applications, and other requirements apply to each type of award individually.

Requirements for SBIR and STTR Awards

- The applicant organization, as well as the applicant, must meet eligibility requirements for small business grants.
- All research supported by SBIR and STTR awards must take place within the United States.
- The applicant must control access to its research facilities, provide appropriate maintenance, secure data collected during the research, and otherwise protect research equipment and resources.
- To be eligible for Phase II awards, the small business must have been awarded a Phase I award and must have demonstrated the feasibility of its product during the term of the Phase I award.

Additional Requirements for SBIR Awards

- The individual named as the principal investigator must be employed by the applicant organization at at least 51% effort

Additional Requirements for STTR Awards

- The individual named as the principal investigator may be employed by the collaborating research institution and must spend a minimum of 10% effort on the work specified in the application.
- If the individual named as the principal investigator is employed by the collaborating research organization, he or she must have a formal appointment with or commitment to the applicant organization.
- The applicant organization must perform at least 40% of the research proposed in the application, and the collaborating nonprofit organization must perform at least 30% of the research. The percentage of each organization's contribution is based on its contribution to the project budget.

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Applying for SBIR/STTR Awards

Applications for SBIR and STTR awards may be submitted on or before April 1, August 1, and December 1 of each year.

Potential applicants are encouraged to speak with PDs before they submit applications so as to ensure that they are eligible for an SBIR or STTR award under the statutory guidelines. In most cases, applications are initially

funded for Phase I, and only Phase I awardees are eligible to participate in Phase II.

Applicants may, however, request funds for Phase I and Phase II work in a single application. Awards issued for such applications are called Fast Track awards.

Using the Fast-Track Process

The SBIR/STTR program provides an expedited submission and review process - the Fast Track process - for Phase II applications. Under this system, applicants submit plans for both Phase I and Phase II work in a single application, and reviewers consider the merit of the work proposed for both stages.

This process is intended to reduce or eliminate the gap between Phase I and Phase II funding and to encourage rapid transition from the "proof of concept" phase into an expanded development and commercialization phase. It can be used to speed the review and award process for applications that:

- Propose work that is significant value in cancer research and treatment.
- Propose work with high potential for commercialization.
- Provide sufficient preliminary data to clearly define milestones that would provide proof of feasibility

An application submitted for Fast Track funding must:

- Include clear measurable milestones to be achieved before Phase II funding is made available.
- Include a product development plan, limited to ten pages, which defines the commercial potential based on analyses of the market and competing products or services.

In discussing the Fast Track process with applicants, PDs should point out its limitations. In particular, specifying the product development and projecting costs may be difficult without having completed Phase I work, and these uncertainties may affect reviewers' judgments of the application. If members of the SRG are not sufficiently confident that the applicant can achieve the Phase I milestones, they may disapprove the Phase II component and review and score only the Phase I component.

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Communicating with Applicants

The PD's responsibilities for communicating with applicants for SBIR/STTR funds, both before awards are issue and afterward, are much the same as is the case with applicants for traditional grants. There are, however, some important differences.

In general, the organizational environment of applicants for SBIR/STTR funds is likely to be quite different from that of applicants for traditional grants. Applicants for SBIR/STTR funds are less likely to be affiliated with universities or

other research organizations, and, hence, less likely to benefit from in-house expertise in grant management.

Thus, PDs and NCI GMSs may need to be especially careful in ensuring that all details of the application and the specific conditions of the award are in order before an award is issued. PDs may also need to communicate more frequently and in more detail as Phase I ends and applicants are considering applications for Phase II awards.

Communicating with Applicants before Awards Are Issued

For the most part, pre-award communication between PDs and SBIR/STTR applicants mirrors communication between PDs and applicants for traditional grants. The issues to be addressed are described in Communicating about Applications Prior to Submission. Create link to heading containing this phrase in Chapter 1.

Communicating with Applicants after Awards Are Issued

As with pre-award communication, most aspects of post-award communication with SBIR/STTR grantees are the same as those carried out with grantees to whom traditional awards were issued. There are, however, some important differences.

In post-award communications with PIs, PDs may want to discuss:

The success of Phase I work as the basis for a Phase II application.

The PD and the PI should attempt to determine whether scientific progress in Phase I has been sufficient to justify Phase II funding. If feasibility has not been clearly demonstrated, the PD may recommend that the PI apply for a new Phase I grant. A thorough discussion of scientific progress during Phase I is especially important for Fast Track grantees as the administrative responsibility for determining whether the agreed-upon milestones have been reached rests with the PD.

A thorough discussion of scientific progress during Phase I is especially important for Fast Track grantees as the administrative responsibility for determining whether the agreed-upon milestones have been reached rests with the PD.

Conversion of an SBIR or STTR award to a cooperative agreement (U43 or U44).

PDs may determine that government resources would help to ensure the success of the work proposed in the application. PDs should present this option to the awardee. If the awardee agrees that such an arrangement would be desirable, the PD may recommend conversion of the grant to a cooperative agreement.

In most cases, such a conversion would take place after Phase I is completed and before a Phase II award is issued. Occasionally, however, assessments of progress and the need for additional resources may indicate that converting a grant to a cooperative agreement during Phase I would be desirable.

For more information about converting grants to cooperative agreements, see Converting Grants to Cooperative Agreements.

The development of a Phase III business plan.

To help grantees seek Phase III funding, PDs should inform small business awardees of potential resources that may be available for their specific needs. Such Phase III activities may include establishing websites listing new products made possible by SBIR/STTR grants and holding marketing conferences during which grantees demonstrate their products. Such conferences may help expedite the adoption of these products in the marketplace.

More generally, PDs should maintain contact with SBIR/STTR grantees to track the outcome of Phase II funding. Success stories should be reported to the SBIR Special Program Officer in the NIH Office of Extramural Research.

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Using Contracts to Achieve SBIR/STTR Goals

In addition to supporting SBIR applications through grants, NCI establishes contracts as a means of achieving the goals of the SBIR program. A contract mechanism should be considered when, and only when:

- Significant direction by NCI staff is required for the execution of the project.
- A distinct deliverable-such as an instrument, software, or data-is expected.

PDs who plan to serve as project officers for an SBIR contract must have successfully completed the project officer training course. These courses are presented at least twice each year. The Administrative Resource Center notifies NCI about the dates and times of these courses by email.

The PD's division and the EC must approve the concept for the contract, and notices about the contract opportunity must be published in the NIH contract solicitation, which is published once each year. Thus, planning the approval

process so as to meet the publication deadline is essential.

Applications are reviewed by a special review group convened by DEA, according to standard contract procedures.

For more information about the use of contracts, see http://rcb-intranet.nci.nih.gov.

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About This Site

What is the purpose of this site?

To provide NCI staff with an easy and up-to-date reference that presents clear guidance on procedures and policies related to grants and cooperative agreements. Such information will also be valuable for the staff in responding to questions from outside the institute. The site provides a one-stop shop for grants management information and helps NCI staff navigate the wealth of information at the NCI.

Who manages this site?

The NCI's Extramural Advisory Board is responsible for managing the contents and updating the Web site.

Best Practices Subcommittee Members

Who is this site designed for?

New NCI staff members who are learning the details of grants review and administration and other staff members who support and manage extramural research. This site provides a reliable resource that permits staff members to check details or clarify specific issues.

What is on this site?

This is the encyclopedia of operating procedures for the grants process in NCI. It is a comprehensive and logical description of how, why, when, and with whom documents must be filed and a quick reference for clarification of any specific issues.

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